

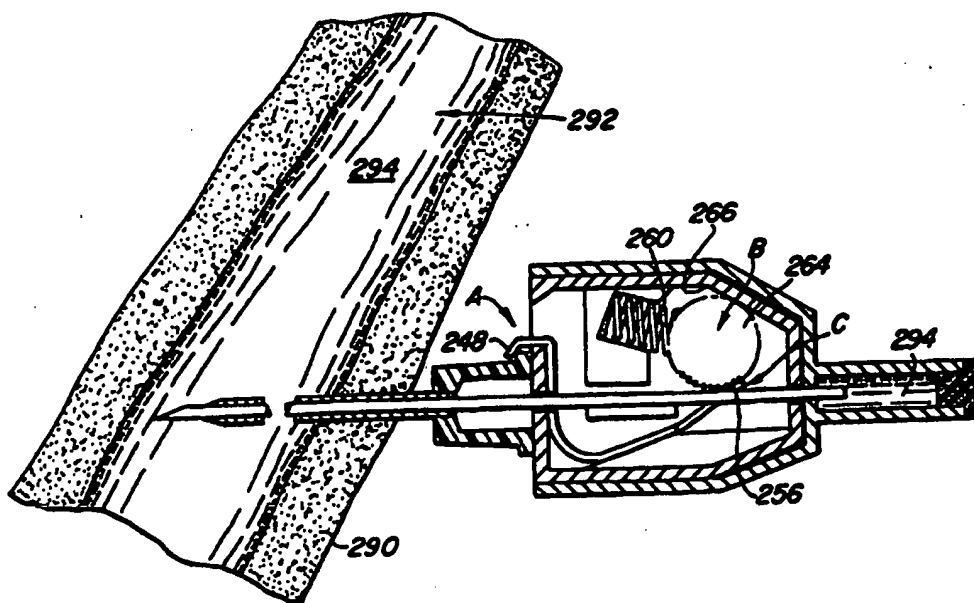
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(54) Title: SAFETY CATHETER



(57) Abstract

A safety catheter (222) includes a pivoted cam (256) and gripping wheel (264) within a housing. As the catheter needle is withdrawn from the catheter the needle point (214) is captured and locked within the housing, reducing the risk of needle stick injuries. When locked, the cam prevents the needle tip from being pushed out of the bottom of the housing, and the gripping wheel prevents the needle from being pulled out of the top of the housing. The sharp needle point is automatically covered and safely contained in the housing as it is withdrawn from the catheter. A retainer (246) holds the catheter onto the housing until the needle point is safely withdrawn into the housing, so that the catheter cannot be used until the needle point is captured.

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DESCRIPTION

SAFETY CATHETER

BACKGROUND OF THE INVENTION

Catheters (i.e., a small tube or needle typically inserted into a vein) are widely used in hospitals to intravenously provide fluids such as blood, plasma, medication, etc. A catheter typically allows a number of intravenous (IV) tubes to be interchangeably connected, and is often left in a patient's arm even when not used, so that additional punctures need not be made for subsequent IV tubes or applications.

Catheters are inserted into the patient with a large-bore stylet or needle. In the most common configuration, the catheter is sold in a sterile pack with the catheter surrounding the needle. A removable plastic needle cover or cap may also be provided around the catheter and needle. In use, the plastic needle cover is first removed, the needle is used to puncture the patient's skin, and the needle and associated catheter are pushed into the puncture. The needle is then withdrawn from the patient and temporarily placed nearby while the catheter is held in place within the puncture site. Then, the catheter is taped to the patient and connected to the infusion set or other lines.

The need to immediately tape and connect an IV catheter generally takes priority over safe needle handling and disposal. The used needle may then be inadvertently left uncapped on a tray, bedsheet, cart, etc. Such a loose sharp instrument creates a significant safety risk to patients and medical personnel. Various types of so-called safety IV catheters have been previously provided to counter this problem. These devices usually include mechanisms designed to prevent needlesticks. However,

conventional safety IV catheters tend to be bulky, difficult to use, and/or expensive.

Accordingly, a need exists for an improved catheter which can be safely, quickly and easily used and disposed
5 of after use. A similar need exists with scalpel blades, hypodermic and other types of needles, trocars, and various other sharp medical instruments, in that these sharp instruments, once used and carrying blood or body fluids, are potential sources of infection from sticking
10 accidents.

STATEMENT OF THE INVENTION

To these ends, a point lock or cover for a surgical instrument includes a housing, a gripper wheel for engaging the free end of the sharp or needle, a wedge for
15 engaging the gripper wheel, and a biasing element or spring for urging the wedge and the gripper wheel into engagement.

The wedge cooperates with the gripper wheel such that, upon insertion of the free end of a needle into the
20 housing, the gripper wheel exerts a force against the free end. A component of that force is perpendicular to the longitudinal axis of the needle. Thus, a longitudinal movement of the needle tending to withdraw the free end of the needle from the housing causes the component of force
25 perpendicular to the longitudinal axis of the needle to increase. The needle is therefore frictionally locked against withdrawal from the housing. A sliding housing over a chassis allows a needle to be unwound from a syringe.

30 Also to these ends, an improved IV catheter, includes a point lock or cover for covering the point of a sharp instrument, i.e., a needle, trocar, scalpel, etc. The point lock includes a housing, a wheel and a wedge surface. Once locked, the point lock prevents the sharp
35 needle point from being withdrawn from the housing. The instrument point or edge is therefore safely and virtually

permanently contained within the housing. A retainer is advantageously provided to prevent separation of the point lock and the catheter until the catheter needle tip is safely withdrawn into the point lock.

- 5 Accordingly, it is an object of the invention to provide a device for more safely handling used medical or surgical instruments including needles, scalpels, trocars, catheters, etc.

BRIEF DESCRIPTION OF THE DRAWING

- 10 In the drawings, wherein similar reference characters denote similar elements, throughout the several views.

Fig. 1 is an exploded perspective view of a preferred embodiment of the present sharp cover;

- 15 Fig. 2 is a perspective view of the cover or cap of Fig. 1, positioned to receive the free end of a hypodermic needle through a funnel-shaped sharps guide;

Fig. 3 is a section view taken along line 3-3 of Fig. 2;

- 20 Fig. 4 is a section view taken along line 4-4 of Fig. 3;

Fig. 5 is a section view similar to Fig. 3, but showing the free end of a needle inserted into the cover;

- 25 Fig. 6 is an enlarged partial section view of the cover of Fig. 5 showing a preferred gripper in engagement with a the needle after attempted withdrawal of the needle;

Fig. 7 is a partial section view of a conventional IV catheter kit including a catheter, needle, and needle cover;

- 30 Fig. 8 is a partial section view of a new IV catheter having a needle lock or cap according to the present invention;

Fig. 9 is a partial section view of the present IV catheter and needle inserted into a patient;

- 35 Fig. 10 is a partial section view thereof with the needle point retracted into the needle lock;

Fig. 11 is a partial section view thereof showing the IV catheter remaining in the patient and with the needle locked into the point lock and detached from the IV catheter;

5 Fig. 12 is a section view of the needle lock taken along line 12-12 of Fig. 11.

Fig. 13 is a longitudinal section view of a safety catheter unit or assembly having a catheter retainer;

Fig. 14 is a perspective view of the needle assembly
10 of the catheter assembly of Fig. 13;

Fig. 15 is a section view of the needle cover or point lock of the catheter assembly of Fig. 13;

Fig. 16 is a front elevation view of the locking arm of the catheter assembly of Fig. 13;

15 Fig. 17 is a side elevation view thereof;

Fig. 18 is a rear elevation view thereof;

Fig. 19 is a front elevation view of the catheter assembly of Fig. 13;

Fig. 19A is a rear end view of a full ring Luer lock
20 on a standard catheter;

Fig. 19B is a partial side elevation view thereof;

Fig. 20 is a side section view of the catheter assembly of Fig. 13 in use, inserted into a blood vessel;

Fig. 21 is a side section view illustrating the
25 locking features of the catheter assembly of Fig. 13;

Fig. 22 is a section view of an alternative embodiment safety catheter assembly, with the catheter and needle positioned for placement into a patient;

Fig. 23 is a section view of the embodiment of Fig. 22
30 with the catheter separated from the catheter assembly housing;

Fig. 24 is a perspective view of the retainer shown in Figs. 22 and 23;

Fig. 25 is a section view of another embodiment,
35 showing the catheter secured onto the catheter assembly housing;

Fig. 26 is a section view of the embodiment of Fig. 25 with the catheter separated from the housing;

Fig. 27 is a perspective view of the retainer shown in Figs. 25 and 26;

5 Fig. 28 is a front elevation view of yet another preferred embodiment;

Fig. 29 is a section view taken along line 29-29 of Fig. 28, and showing the needle and catheter ready for placement into a patient, with the catheter secured onto
10 the catheter assembly housing;

Fig. 30 is a cross-sectional end view thereof;

Fig. 31 is a front elevation view showing the push button of Figs. 28-30 in the released position; and

Fig. 32 is a section view thereof, with the alternative positions of certain components indicated in phantom
15 line.

Fig. 33 is a perspective view of a needle point cover used in applications where it is desirable to separate the needle from the syringe;

20 Fig. 34 is an exploded perspective view thereof;

Fig. 35 is an enlarged partial section view of a needle inserted into the sliding outer cover, with the splines of the needle hub engaged with the splines of the sliding outer cover of the present safety device;

25 Fig. 36 is a top view of the sliding outer cover shown in Figs. 33-35;

Fig. 37 is a section view of the sliding outer cover taken along line 37-37 of Fig. 36;

30 Fig. 38 is a section view of the sliding outer cover taken along line 38-38 of Fig. 37;

Fig. 39 is a side elevation view of the housing; and

Fig. 40 is a side elevation view of an alternative embodiment having a combined spring and seal block.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

35 Referring now to the drawings, as best shown in Figs. 2 and 5, the present cover 10 is configured to receive and

permanently cap the free end of a hypodermic needle, or other sharp device. As shown in Fig. 2, a hypodermic syringe and needle assembly 20 includes a needle 22 having a free end 24, a restrained end 25, an outer surface 26, and a longitudinal axis 27. Free end 24 has a sharp tip 28 to pierce the skin.

Referring now to Fig. 1, the cover 10 includes a housing 30, a gripping wheel 70, a spring or biasing element 80, and preferably a seal block 90. The housing 30 is advantageously provided as a two-part plastic assembly having a first section 32 and a second section 34. The housing 30 includes top and bottom ends 36 and 38. A sharps receiving portion 100 is provided at the top end 36. A conical metal liner 101 is attached (bonded, snapped or molded-in, etc.) to the receiving portion 100 to prevent sharp instrument tips from sticking into the plastic receiving portion surface.

As best shown in Fig. 3, the housing 30 is also provided with a first set of substantially opposed lateral interior surfaces 40 and 42, an upper interior surface 44 and lower interior surface 46. As best shown in Fig. 4, the housing 30 also includes a second set of substantially opposed lateral interior sidewalls 48 and 50. Lateral interior surfaces 40 and 42 and interior sidewalls 48 and 50 each extend between upper and lower interior surfaces 44 and 46 to define an interior cavity 60. The gripping wheel 70, biasing element 80 and seal block 90 are contained within the cavity 60.

The lateral interior surface 40 includes an upper planar portion 52 and lower portion 54. As best shown in Fig. 5 upper planar portion 52 is configured to engage the free end 24 of the needle along tangent 26A upon insertion of free end 24 into the cover 10. The lower portion 54 defines a recess 62 provided to position the sealing element 90 adjacent the lower interior surface 46. Upon insertion of a needle, the needle tip 28 embeds into the seal block 90.

The lateral interior surface 42 includes an upper angled portion 56 and a lower planar portion 58. The upper angled portion 56 together with upper planar portion 52 form a wedging element 64 configured to cooperate with the gripping element 70 before and after insertion of free end 24 of the needle into the cover 10. As best shown in Fig. 3, the upper angled portion 56 inclines towards the lateral interior surface 40 as the upper angled portion 56 extends from the lower planar portion 58 towards the first end 36 to define an area of convergence or a wedge zone 66. The lower planar portion 58 is substantially parallel to the upper planar portion 52.

The gripping element 70 is substantially cylindrical in shape, having two flat ends 72 and 74 and a substantially arcuate gripping surface 76. Referring to Fig. 4, the gripping element 70 is positioned within interior cavity 60 with the flat ends 72 and 74 closely adjacent to the interior sidewalls 48 and 50. The distance between sidewalls 72 and 74 is sufficient to permit the gripping element 70 to slide within cavity 60 between the upper and lower interior surfaces 44 and 46, while substantially maintaining its alignment.

Referring now to Figs. 3 and 5, the dimensions of gripping surface 76 (vis-a-vis wedging element 64 and the needle) are shown proportionally in the drawings and are selected to ensure that gripping surface 76 (in response to the biasing action of biasing element 80) remains in simultaneous engagement with the upper planar portion 52 and the angled portion 56 before insertion of free end 24 of the needle into the housing 30, and to ensure that gripping surface 76 (in response to the biasing action of biasing element 80) remains in simultaneous engagement with the outer surface 26 of the needle along tangent 26B and angled portion 56 after insertion of the needle into the housing 30.

The substantially arcuate gripping surface 76 facilitates the foregoing described purposes while at the same

time ensuring that gripping element 70 does not engage the free end 24 of the needle in such a manner as to prevent free end 24 from being fully inserted into the interior cavity 60 as best shown in Fig. 5. It will be understood by those skilled in the art that other configurations of gripping element 70 may also facilitate these purposes.

Preferably, the biasing element 80 is an annular shaped elastomer, having two flat ends 82 and 84, a substantially round outer surface 86, with a hole 88 extending between the ends 82 and 84. As shown in Fig. 4, the biasing element 80 is positioned within the interior cavity 60, between the gripping element 70 and the sealing element 90, such that its ends 82 and 84 are adjacent the sidewalls 48 and 50 and outer surface 86 engages gripping element 70.

Referring now to Figs. 3 and 5, the outer diameter (uncompressed) of the biasing element 80 is sufficiently large to ensure that it constantly acts upon the gripping element 70, urging the gripping element 70 towards the first end 36. This causes the gripping surface 76 to engage the upper planar portion 52 and the angled portion 56 as described above.

Assembly of the cover 10 is accomplished by compressing outer surface 86 of the biasing element 80 sufficiently to enable the gripping element 70, the biasing element 80 and the sealing element 90 to be inserted into interior cavity 60. Thereafter, first and second sections 32 and 34 of housing 30 are joined together using any conventional methods.

The interaction between the biasing element 80, the gripping element 70 and the wedging element 64 prior to insertion of free end 24 into interior cavity 60 is shown in Fig. 3. The biasing element 80 exerts an upward force on the gripping element 70. This upward force drives the gripping element 70 into engagement with the upper planar portion 52 and the angled portion 56, effectively wedging the gripping element 70 therebetween. The pressure

exerted against gripping element 70 at the interface between gripping element 70 and angled portion 56 includes a component of force which is perpendicular to the upper planar portion 52. This component of force is offset by an opposing force at the interface between the gripping element 70 and the upper planar portion 52.

As the free end 24 of the needle is inserted into interior cavity 60, it is wedged between the upper planar portion 52 and the gripping element 70 thereby displacing gripping element 70 and causing the gripping element 70 to move downwardly towards the bottom end 38. As shown in Fig. 5, the free end 24 is engaged by the upper planar portion 52 along tangent 26A and engaged by the gripping element 70 along tangent 26B. The downward motion of gripping element 70 causes biasing element 80 to further compress thereby increasing the amount of pressure exerted by the biasing element 80 against the gripping element 70. This in turn increases the pressure at the interface between the gripping element 70 and the angled portion 56 which, in turn, increases the pressure at the interface between the upper planar portion 52 and the free end 24 along tangent 26A and at the interface between the gripping element 70 and free end 24 along tangent 26B.

Any attempt to withdraw needle 22 from the interior cavity 60 after insertion will generate opposing frictional forces at the interface between the upper planar portion 52 and free end 24 and at the interface between gripping element 70 and free end 24. The frictional force exerted by free end 24 upon gripping element 70 will tend to drive gripping element 70 upwardly towards the first end 36 thereby increasing the pressure exerted against the gripping element 70 at the interface between the gripping element 70 and the angled portion 56 which, in turn, will increase the pressure exerted both at the interface between the upper planar portion 52 and free end 24 along tangent 26A and at the interface between the gripping element 70 and free end 24 along tangent 26B, thereby

increasing the needle retaining effect of the cover 10. The greater the force applied to needle 22 tending to withdraw the free end 24 from the interior cavity 60, the greater the frictional forces exerted upon the free end 24
5 resisting such movement. The needle therefore becomes permanently locked within the housing.

The biasing element 80 is selected to allow surgical sharps to be manually inserted into the interior cavity 60 without difficulty while at the same time ensuring that
10 any attempt to withdraw such sharp will be opposed by sufficient frictional forces as described above. While, in the preferred embodiment, the biasing element 80 must be sufficiently large to render the cover 10 operable, the biasing element 80 must not be so large or stiff as to
15 prevent the needle 22 from being inserted into interior cavity sufficiently to ensure that tip 28 fully engages sealing element 90. Preferably, the outer diameter 87 (compressed) of the biasing element 80 as measured in a plane transverse to upper planar portion 52 must be less
20 than the distance between the tangent 26B to outer surface 26 and lower planar portion 54. To further facilitate complete engagement of the tip 28 and sealing element 90, the biasing element 80 may be positioned within the interior cavity 60 vis-a-vis the gripping element 70 such that the
25 pressure at the interface between gripping element 70 and the biasing element 80 urges the biasing element 80 away from the upper planar portion 52, as shown in Fig. 5.

The needle retaining effect is enhanced by the gripping surface 76, of a plurality of evenly-spaced teeth 78,
30 each of which extends between ends 72 and 74. The teeth 78 provide sharp edges 79 and are backwardly curving, as best shown in Fig. 6, to improve gripping. The teeth 78 (and the rest of gripping element 70) are preferably composed of a material which is hard enough to gouge the
35 outer surface 26 of free end 24. As a result, attempts to withdraw the needle 22 from interior cavity 60 drive the teeth 78 into the outer surface 26 thereby creating a

mechanical interference which precludes withdrawal of the needle 24. The free end 24 of the needle 22 is thus permanently locked into the cover 10. The gripping surface 76 and upper planar portion 52 may, alternatively, be roughened or scored to improve the needle retaining effect.

To guard against the hazardous and uncontrolled accumulation of bodily fluids which may reside within used sharps, e.g., hypodermic needles, the cover 10 is also provided with sealing element 90. Upon insertion of free end 24 of the needle 22 into the interior cavity 60, the tip 28 engages and becomes embedded within the sealing element 90 thereby retaining any such residual bodily fluids within the interior of the needle 22. Preferably, the sealing element 90 is a slab of material which is sufficiently soft to allow penetration of tip 28 into the sealing element 90 while at the same time providing a proper seal of the needle tip. In the preferred embodiment, the sealing element 90 is sized to complement the lower interior surface 40 and to reside with the recess 62. The needle port 108 is positioned over the sealing element 90, so that the needle tip will project into the sealing element.

The housing 30 is provided with a sharps receiving portion 100 at its first end 36. As shown in Figs. 2, 3, and 4, the sharps receiving portion 100 includes sharps guide 102 having a funnel-shaped recess with a maximum diameter 104 on the top end 36 and a minimum diameter 106 at the bottom of the funnel-shaped recess. The minimum diameter 106 defines an eccentric needle port 108 which is sized to receive the free end 24 of a needle 22. The needle port 108 is positioned such that upper planar surface 52 is tangent to the outer diameter of needle port 108. The free end 24 of the needle can accordingly be placed through the needle port 108 without difficulty while simultaneously being properly positioned within the

interior cavity 60 between the upper planar portion 52 and the gripping element 70.

A plurality of covers 10 may be mounted in an array on a flat bottom container which can be placed on a surgical table, cart, etc. The bottom end 38 of each cover 10 may be attached to the container, using any suitable means, so that the sharps receiving portion 100 of each cover 10 is directed substantially upward. Alternatively, the container may present the sharps receiving portions 100 at an angle to the horizontal. The bottom of the covers container may be provided with an adhesive or other suitable means to resist unwanted movement during use.

Thus, the present cover 10 enables surgeons, nurses, and other operating room personnel to control used sharps, during and after surgical operations in such a way that medical hazards are not presented to the operating room staff or to the patient while further ensuring the permanent disposal of hypodermic needles and the like.

A safety catheter having similar advantages, as shown in Fig. 7, has a needle 122 is surrounded by a conventional IV catheter 120, and covered by a removable needle cap 124. A male fitting 126 on the needle 122 typically engages a female fitting 128 (e.g. a Luer fitting) on the catheter 120, as is well known in the art.

In use, the cap 124 is first removed to expose the point 125 of the needle 122. The needle point 125 is used to puncture the patient's skin, and the needle 122 and catheter 120 are then slowly pushed into the puncture site. The catheter 120 is then held in place within the puncture site while the needle is withdrawn. When the needle has been completely withdrawn, the catheter remains in the patient, and is connected to an IV tube. However, the needle poses a needle stick hazard until it is properly disposed of.

The present safety catheter greatly reduces the needle stick hazard associated with IV catheters. As shown in Fig. 8, the present safety catheter includes an IV catheter

ter 130 and needle cap 134, which may be the same as the conventional catheter and needle cover shown in Fig. 7. The IV catheter 130 is fitted onto a point or needle lock 138 having a housing 140. The outer surface of the housing 140 may be smooth or knurled. As shown in Fig. 8, the housing 140 has a polygonal shape which includes two tapered surfaces 142. These tapered surfaces 142 provide thumb and finger surfaces for grabbing and holding the housing 140 in place.

10 The housing 140 includes a fitting 144 similar to the fitting 126 of the conventional catheter needle shown in Fig. 7, for joining the housing 140 and IV catheter 130. Within the housing 140 a stay 160 projects from the housing wall and contacts a needle 132 which extends
15 entirely through the housing 140 and IV catheter 130. An inner wall 147 slants toward the needle 132 at the top of the housing (The safety catheter in Fig. 8 is shown inverted). The needle 132 may be similar to, but is longer than the needle 122 shown in Fig. 7.

20 A cam 148 within the housing 140 includes a lower leg 156 and an upper leg 158, and pivots on a pin 154. As shown in Fig. 12, the width of lower leg 156 is approximately the same as the interior space 146 within the housing 140. The upper leg 158 is about one half as wide
25 or thick as the lower leg, so that the needle 132 may extend underneath the upper leg 158. The full width of the lower leg 156 prevents the needle 132 from extending into the opening 151, unless the cam is positioned out of the way, as shown in Fig. 8.

30 A gripping wheel 150 is positioned within the housing 140 between the upper leg 158 of the cam 148, the housing wall, and a spring 152. Preferably, the gripping wheel 150 is formed of metal, hard plastic, or other substantially non-compressible material. The perimeter of the
35 wheel 150 is knurled, roughened or serrated. The wheel 150 is too wide to pass underneath the upper leg 158 of the cam 148. The spring 152 positioned within a spring

bore in the housing, pushes the wheel 150 against the upper leg 158. The gripping wheel 150 itself is not attached to any portion of the housing 140. Rather, it is held in place by the spring 152, the upper leg 158 and the housing wall, and can shift position.

When the needle lock 138 is in the position shown in Fig. 8, the spring 152 pushes against the gripping wheel 150. The spring force presses the gripping wheel against the upper leg 158 of the cam 148, causing the cam 148 to rotate about pivot 154 in a clockwise direction, until the lower arm 156 contacts the needle 132 and presses against it. A slight frictional force is thus created between the cam 148, the stay 160, and the needle 132, which helps to prevent the needle 132 from prematurely backing out of the needle lock.

In use, the needle cover 134 is first removed to expose the needle 132. The needle and catheter are then inserted into a patient's arm 155 or other body area, as with conventional IV catheter kits, as shown in Fig. 9.

The needle lock housing 140 is held preferably by clasping the tapered surfaces 142 of the housing between the thumb and forefinger of one hand. With the housing held in place, the needle 132 is withdrawn from the catheter 130. The catheter may optionally be taped down onto the skin.

As the point 135 of the needle 132 is pulled back into the housing 140 and passes the lower leg 156 of the cam 148, the shaft of the needle 132 no longer stops the rotation of the cam 148 about the pivot 154. The force of the spring 152 against the gripping wheel 150 and the upper leg 158 cause the cam 148 to pivot in a clockwise direction. This movement causes the lower leg 156 to move into a position to block the lower opening 151 of the housing 140, as shown in Fig. 10. At the same time the gripping wheel 150 shifts upwardly along the slanted wall 147 and wedges between the shaft of the needle 132 and the wall 147. The spring 152 holds the gripping wheel 150 in

this wedged position. The knurled perimeter of the wheel 150 grips the shaft of the needle 132 and the slanted wall 147, preventing the wheel from turning counter clockwise. As the wheel is engaged to both the needle shaft and the wall 147 and cannot turn, the needle 132 cannot be pulled any farther out of the housing. (The geometry allows the wheel to turn or roll clockwise, allowing the needle to be pushed further through the housing, but not counter clockwise, which would allow the needle to be withdrawn.)

After the wheel 150 wedges into position as shown in Fig. 10, the cam 148 is prevented from pivoting in a counter-clockwise direction, to release the needle point 135, as the wedged wheel 150 blocks movement of the upper leg 158. Thus the lower leg 156 is locked in a position which blocks the opening 151 preventing the needle 132 from being pushed out of the housing 140, and the wedged wheel prevents the needle from being pulled out of the housing. The needle is therefore locked in position. Before the needle is withdrawn, the upper leg 158 prevents the wheel from shifting up into the wedged position, as shown in Fig. 8.

When the needle is securely locked in position, the point of the needle is safely contained within the housing 140. In addition, once the needle has been retracted into the housing, the cam 148 and gripping wheel 150 prevent the needle from either being pulled out of or pushed through the housing 140. The point of the needle is securely and permanently held within the housing reducing the possibility of injury caused by contact with the used needle.

As shown in Fig. 11, after the needle 132 has been retracted into the housing 140, the fitting on the housing 140 may be disengaged from the catheter 130 and an IV connected. The disengaged needle 132 and needle lock 138 may then be safely disposed of, without replacing the needle cap 134.

The present embodiment therefore provides a safe,

efficient and self-contained catheter for protecting the points of used IV needles. Moreover, the needle lock 138 works automatically with the withdrawal of the needle from the IV puncture site. Even if the needle is pulled out of the puncture site very quickly or forcefully, the point 135 will still become locked within the housing 140. The needle lock 138 permits medical personnel to simply insert the needle and catheter, withdraw the needle, and immediately dispose of the used needle without substantial risk of injury, and without the taking of time and risks of recapping or other steps. In addition, the needle lock 138 can be used with standard existing catheters. Standard needles may also be used, if they are long enough to extend through both the catheter 130 and needle lock 138. The needle lock 138 is also highly tamper resistant. Once the needle 132 becomes locked within the housing 140, it is exceptionally difficult or impossible to remove the needle.

Preferably, the housing 140 is made with a thin, flat profile, so that the housing 140 may be laid flat against the patient's skin while the catheter is inserted. For convenience and ease of disposal, the housing 140 should be compact and made of a tough material, preferably metal or a hard plastic. The openings in the housing 140 through which the needle 132 passes should be made to approximate the diameter of the needle itself, to insure that the needle is securely held within the housing 140.

As shown in Fig. 13, another safety catheter assembly or unit 200 includes a needle assembly 202, a needle point lock 240 and a catheter 222. As shown in Fig. 14, the needle assembly 202 has a housing cover 204 forming an open interior space, to receive the needle point lock 240. A preferably clear tube 208 extends from the back wall 210 of the housing cover 204, and is capped off with a vent 220 made of an air porous material. The tube 208 forms a cylindrical flash back chamber 206. The bore 215 at the back end 218 of a needle 212 opens into the flash back

chamber 206. The needle passes through and is held in position by the back wall 210, extends forward through and projects substantially beyond the housing cover 204, to a point 214. The length of the shaft 216 of the needle 212 is selected to cooperate with the catheter 222 used and the particular medical application of the safety catheter unit 200.

Referring once again to Fig. 13, the catheter 222 has a point 226, on a catheter shaft 224, having a hub 228 at the back end. The interior of the hub 228 has a fitting 230, such as a Luer fitting, adapted to connect with intravenous or other tubes or fittings. As shown in Fig. 19, the hub 228 of the catheter 222 includes Luer lock flanges 232, but may otherwise preferably be a full ring Luer lock 299 as seen in standard catheters.

Referring to Fig. 15, the needle point lock 240 has a housing enclosing a locking mechanism 272. The housing has a floor 280 and continuous walls, and a cover (not shown). A front opening 244 is provided in the flat front wall of the housing. A front needle hole 268 passes through the front wall of the housing 242, below the front opening 244, and is aligned with a rear needle hole 270 in the rear wall of the housing 242.

A spring block 284, a guide 286, and a shelf 282 are attached to or integral with the floor 280 and/or walls of the housing 242. The shelf 282 has a height which is only a fraction of the height of the housing 242, while the spring lock 284 and guide 286 preferably extend entirely from the floor 280 to the cover.

As shown in Figs. 16, 17 and 18, a locking arm 246 has a hook 248 formed by prongs 250 on opposite sides of a cut out 252. The locking arm 246 is positioned within the housing 242 with a tab 256 on the locking arm 246 extending over the shelf 282. A needle slot or hole 258 is provided in the front leg 254 of the locking arm 246.

Referring to Figs. 13 and 15, a spring 260 positioned within a spring bore 262 extends to push against a wheel

264, urging the wheel 264 against a ramp 266 on the housing 242, and against the tab 256 on the back end of the locking arm 246. The wheel 264 has a toothed, knurled, roughened or other engagement/friction surface.

5 Referring to Fig. 13, with the safety catheter 200 assembled and ready for use (e.g., as it would be provided in a sterile package), the housing cover 204 of the needle assembly 202 is positioned over and around the housing 242 of the needle point lock 240, with the needle 212 of the
10 needle assembly 202 extending through the rear needle hole 270, through the needle slot 258 in the locking arm 246, through the front needle hole 268, and into and through the catheter 222. The diameter of the needle 212 is selected to fit closely within the catheter shaft 224, and
15 the length of the needle 212 allows the point 214 to project just beyond the point 226 of the catheter shaft 224, as shown in Fig. 13. With the needle 212 extending through the needle slot 258, the hook 248 on the locking arm 246 is held down, clamping the rear flat surface of
20 the hub 228 of the catheter 222 against the front flat surface of the housing 242. Referring momentarily to Fig. 19, flange stops 234 on the front surface of the housing 242 prevent rotation of the catheter 222, so that the flanges 232 on the hub 228 of the catheter cannot
25 rotate or move out from under the hook 248 of the locking arm 246. If a full ring 299 Luer lock is used, flanges 232 are not needed as catheter rotation will not affect its retention by hook 248 of locking arm 246.

In typical use, as shown in Fig. 20, the safety catheter 200 as it is shown in Fig. 13, is removed from its
30 package. The needle 212, along with the catheter shaft 224 is pushed through the skin and tissue 290 into a blood vessel 292. Blood 294 flows through the hollow needle 212 into the flash back chamber 206. Air in the flash back
35 chamber 206 is displaced by the blood 294 and diffuses out through the vent 220, which allows air, but not blood to pass through. The presence of blood 294 in the flash back

chamber 206 provides a visual indication to the user.

Referring to Figs. 20 and 21, while the catheter 222 is held in position, the needle assembly 202 is pulled back and separates from the needle point lock 240. The locking arm 246, in position A, keeps the needle point lock 240 attached to the catheter 222. The tab 256, in position C, holds the wheel 264, in position B, away from the needle. When the needle assembly 202 is pulled back sufficiently, the point 214 of the needle 212 is pulled within the housing 242, and out of or behind the needle slot 258. As soon as the point 214 clears the needle slot 258, the locking arm 246 springs up (position D in Fig. 21), driven by the spring tension of the locking arm 246 in the housing 242. The needle point lock 240 can then be removed from the catheter 222, so that an intravenous line can be connected to the catheter 222. As the needle slot 258 has shifted upwardly, as shown in Fig. 21, the needle 212 can longer be moved forward out of the housing 242. Trying to push the needle 212 forward, simply drives the point 214 into a solid section of the front leg 254 of the locking arm 246. The needle 212 also cannot be pulled out of the rear of the housing 242, as the upward shift of the locking arm 246, from position A in Fig. 20 to position D in Fig. 21, also pivots or moves the tab 256 at the back end of the locking arm 246 downwardly (from position C in Fig. 20, to position G in Fig. 21), allowing the wheel 264 to engage against the shaft 216 of the needle 212, at position F in Fig. 21. Once released by the movement of the tab 256, the wheel 264, driven by the spring 260, now engages the needle shaft 216 and the ramp 266, rather than the tab 256 and the ramp 266. The roughened or toothed surface of the wheel 264 grips the shaft 216 of the needle 212, and the ramp 266, preventing the needle 214 from moving rearwardly out of the housing 242.

The needle shaft 216 cannot move away from the wheel 264 biased into the shaft 216, as the shaft 216 is supported at the rear needle hole 270, and by the guide 286.

Rearward movement of the needle shaft 216 causes the wheel 264 to move down the ramp 266 and into further and stronger engagement against the shaft 216. The roughened or toothed surface on the wheel 264 prevents slipping between
5 the needle shaft 216 and wheel 264. As a result, the point 214 of the needle 212 is safely contained within the housing 242. The needle point lock 240 and needle assembly 202 (connected by the needle shaft 216) can then be safely discarded.

10 Since the catheter 222 cannot be accessed until the needle assembly 202 is withdrawn, (thereby automatically safely locking the needle point 214 within the needle point lock housing 242) the point locking safety feature does not rely on the attention of the user.

15 Turning now to Figs. 22-24, in an alternative embodiment the locking arm 246 shown in Figs. 13 and 16-17 may be replaced by a retainer 302 pivotably mounted within a housing 320. Referring to Fig. 24, the retainer 302 has a back end 304 having a back slot 306. A retainer front
20 end 312 is joined to the back end 304 by an arm 308. A front leg 318 on the front end 312 has a front slot 316 and a hook 314. A pivot pin 310 extends laterally from the arm 308, to pivotably mount the retainer 302 within the housing 320.

25 Referring to Fig. 22, a spring 260 urges a gripping wheel 264 onto a ramp surface 266, and into engagement with the back end 304 of the retainer 302. The hook 314 extends out of a top opening 322 in the housing 320. The hook 314 engages the hub 228 of the catheter 222, preferably
30 bly engaging the Luer lock flanges 232, or alternatively the ring of a full ring Luer lock as is often used on standard catheters. The needle 132 extends through the housing 320, and through the back slot 306 and front slot 316 in the retainer 302. A tapered front fitting 144 on
35 the housing 320 positions the hub of the catheter. A fitting 324 on the needle 132 may engage a tapered rear bore 326 in the housing 320, for added support.

As shown in Fig. 22, the safety catheter 300 is ready for use. With the retainer 302 in position G as shown, the catheter 222 cannot be separated from the housing 320. Accordingly, after the needle and catheter are placed into a patient, the needle must be withdrawn to access the catheter. Referring to Fig. 23, as the needle 132 is withdrawn, the floor 317 of the front slot 316 bears and slides against the underside of the needle, as it is urged into engagement of the needle via the spring 260 and wheel 264. However, this creates only a slight drag force which does not significantly effect withdrawal of the needle. Referring to Fig. 23, when the point 135 of the needle 132 moves behind the front slot 316, the retainer 302 pivots upwardly, releasing the hook 314 from the catheter 222. The catheter 222 and housing 320 can then be separated, so that connections may be made to the catheter. At the same time, the wheel 264 moves down the ramp 266 and engages the needle 132, and prevents further withdrawal of the needle from the housing 320. The needle cannot be pushed forward out of the housing 320 as the front housing opening 328 is now blocked by the front leg 318 of the retainer 302. Accordingly, the point 135 of the needle 132 is permanently secured within the housing 320, for safer handling and disposal.

Referring to Figs. 25-27 an alternative embodiment improves the safety catheter described in U.S. Patent No. 5,328,482, incorporated herein by reference. U.S. Patent No. 5,328,482 describes a safety catheter using a lever arm of stiff material, formed in the general shape of a broad U of unequal proportions, as shown therein e.g., in Fig. 35. The embodiment 340 shown in Figs. 25-27 allows the locking mechanism of U.S. Patent No. 5,328,482 to be used with a catheter. Referring to Fig. 25, the safety catheter embodiment 340 has a sleeve or housing 342 with a front disk or guard body 344. A housing block 346 and a housing stand 350 extend upwardly and/or inwardly from the walls of the housing 344. A retainer 348 has a hook

354 extending out of the housing 344 to engage and hold the catheter to the housing. A spring 352 urges the retainer 348 to the rear of the housing 344.

Referring to Fig. 22, the retainer 348 includes a rear
5 leg 356, arm 358, front leg 360 and the hook 354. A rear hole 362 in the rear leg 356 aligns with a front hole 364 and the front leg 360.

In use, the safety catheter 340 as shown in Fig. 25 is ready for placement into a patient. The hook 354 retains
10 the catheter onto the housing 344. After placement, as shown in Fig. 26, the needle is withdrawn. When the point 135 of the needle is drawn behind the front hole 364, the retainer 348 pivots or shifts, freeing the hook 354 from the catheter, which can now be separated from the housing
15 344. The spring 352 shifts the retainer 348 into the position shown in Fig. 26. In this position, the point 135 of the needle cannot be pushed forward and out of the housing 344, as it is blocked by the front leg 360 of the retainer 348. The needle may not be withdrawn further
20 from the housing 344, as the rear leg 356 frictionally locks against the needle via the interaction of the angle of the back leg torqued on the needle by the spring 352, as described in U.S. Patent No. 5,328,482.

Referring now to Figs. 28-32, in yet another safety
25 catheter embodiment 378, a slide 390 within a housing 380 has a catch 388. A retainer 382 has a push button surface 394. A tension arm 384 extending from the push button 394, through an opening in the housing 380, has a lip 386 engaged to the catch 388. A spring 400 has one end
30 against a front wall of the housing 380 and pushes the slide 390 rearwardly. A pair of legs 396 with feet 398 extending downwardly or inwardly from the push button 394 overlap tabs 406 on a catheter 402, to secure the catheter to the front of the housing 380.

35 In use, with the safety catheter 378 in the position shown in Fig. 29, the needle and catheter are ready for placement. The tension created by the spring 480 on or

through the slide 390 and retainer 382 maintain them in the positions shown. The catheter cannot be separated from the housing 380, as it is held in place by the legs 396 and feet 398 overlapping the tabs 406 on the catheter.

- 5 After installation, to separate the catheter and housing, the push button 394 is pushed down or inwardly. This movement releases the catch 388 from the lip 386, as shown in Fig. 32. Simultaneously, the feet 398 move downwardly so that they are no longer over the catheter tabs 406.
- 10 The catheter 402 is then free to move forward through the legs 396 and separate from the housing 380. The spring drives the slide 390 rearwardly to automatically withdraw the point 135 of the needle into the housing 380, where the needle may be safely contained for handling and
- 15 disposal, e.g., as described in U.S. Patent No. 4,747,831, incorporated herein by reference. The configuration of the legs 396 or feet 398 may be changed for use with a catheter having tabs or a pull ring.

- Various of the features shown in the drawings may be
- 20 used on the different embodiments described. For example, the needle assembly having the flash back chamber shown in Fig. 13 may also be used on the embodiments shown in the other figures. Different catheter hub configurations may also be used and alternative designs or materials may be
- 25 substituted for the springs shown in the drawings. In addition, other equivalents of the retainers shown and described may also be used.

- Referring to Fig. 33, in certain procedures, such as blood gas sampling, blood is withdrawn with a hypodermic
- 30 syringe and needle assembly 500. However, rather than discarding the entire needle assembly 500 (as is often the case in giving injections), the needle 504 must be removed from the syringe 502. As the shaft 506 of the needle 504 is often very short, there may be little space for the
- 35 medical technician's fingers to grasp, turn and remove the needle 504 after the shaft 506 of the needle 504 is fully

inserted into a safety device, such as the housing 30 shown in Fig. 2.

To better provide for separating the needle 504 from the syringe 502, as shown in Figs. 33-40, a safety device 520 has an outer cover 522 slidably positioned over a housing 540. The cover 522 has longitudinal ribs 524 around its outside circumference. An opening 526 at the top or front of the cover 522 has splines 528 which taper inwardly along a conically tapering inner surface 532. The cover 522 has a housing slot 530, to provide clearance for a ridge section 578 on the housing 540, when the cover is positioned fully over the housing 540, as shown in Fig. 33.

Referring to Fig. 34, the housing 540 has a conical dish surface 542 having a metal liner 544 attached (e.g., bonded shaped or molded in) to the dish surface 542. A needle opening 546 extends through the center of the dish surface 542 and liner 544. The housing 540 has a chassis slot 550 on one side, with a tab slot 552 above the chassis slot 550.

Turning to Figs. 34 and 39, a chassis 560 (preferably molded as a single plastic unit) has a tab 562, a straight wall 574 and an inclined wall 572, in part forming a wheel recess 568. A gripping wheel 564 is positioned within the wheel recess 568. A spring 566 is supported within a spring slot 570 formed by internal chassis walls. The gripper wheel 564 is preferably a steel wheel having a knurled or roughened surface around its circumference (e.g., a cigarette lighter wheel). The spring 566 is advantageously a soft rubber block.

A seal block 576 is contained within the chassis 560 and held in place by chassis walls. The seal block is preferably a soft rubber or plastic material. Preferably, the spring 566 and seal block 576 are combined as a single integral piece, with the spring 566 formed as a protrusion on the block 576, as shown in Fig. 40. The chassis 560 has a top wall 563 having a needle entry opening 565

adjacent to the straight wall 574. With the chassis 560, housing 540 and cover 522 assembled and ready for use, as shown in Fig. 33, the opening 526 in the cover 522; the opening 546 in the housing 540; and the opening 565 in the chassis, are aligned, so the needle point 510 can pass freely through them, in between the straight wall 574 and the gripping wheel 564, and into the sealing block 576. The substantially impenetrable lower wall 567 of the chassis 560 prevents the point 510 from piercing through the chassis.

Turning to Figs. 37 and 38, a recess 534 is formed on the inside of the cover 522 above the housing slot 530, and is adapted to receive the tab 562 on the chassis 560.

The cover 522 is provided with splines 528 preferably matching the number of splines 512 on the hub 508 of the needle 504 (Fig. 33). The splines 528, as shown in Figs. 33, 36, 37 and 38, are spaced apart and oriented to properly intermesh with the splines 512 on the needle hub 508. Typical needles 504 have 4 splines 512. Hence, the cover 522 is also provided with 4 splines 528, although other numbers and configurations may be provided to work with different needles.

In use, the point 510 of the needle 504 is inserted through the opening 526 in the cover 522, through the needle opening 546, and into the chassis 560 wherein it is engaged and locked by the interaction of the wheel 564, spring 566, straight wall 574 and inclined wall 572, as described above in connection with e.g., Figs. 3, 4 and 5. The device 520 is preferably held in a tray or other fixture during needle insertion, to keep hands away from the needle point. Referring to Fig. 33, with the needle 504 fully inserted, there is little or no clearance between the hub 508 of the needle 504 and the front or top surface 523 of the cover 522. Accordingly, ordinarily, it may be difficult to grasp and turn the hub 508 to remove the needle 504 from the syringe 502. However, as the cover 522 is separate from the housing 540 and chassis

560, the cover 522 can be moved upwardly along the shaft 506 of the needle 504, while the housing 540 remains around and captivates the point 510 of the needle 504 towards the hub 512. The splines 528 and tapered surface or inlet 532 on the cover 522 are configured to match and engage the hub 508 and its splines 512. With the cover 522 engaged onto the hub 508, the cover may be turned (counterclockwise) to unwind the hub 508 from the syringe threads 514 at the lower end of the syringe 502. Accordingly, the needle 504 (i.e., the hub 508 and shaft 506) may be separated from the syringe 502 while the point 510 of the needle 504 is captive within the housing 540, to avoid accidental needle sticks.

If the needle is very short, for example, if the needle shaft 506 is approximately the same length as the height of the housing 540, the cover 522 may engage the needle hub 508, even before the point 510 bottoms out in the seal block 576. In this instance, the cover 522 need not (and cannot) be slid towards the syringe 502 to engage the hub 508. Rather, the needle 504 is unwound simply by holding the syringe 502 and turning the cover 522 (with the housing 540 containing the chassis 560 turning with the cover 522). On the other hand, if the shaft 506 of the needle 504 is longer, the point 510 will bottom out within the seal block 576 while the hub 508 is spaced away from the cover 522. In this situation, the cover 522 is pushed up the along the needle shaft to engage the hub 508. If the needle shaft 506 is exceptionally long, the cover 522 will be moved far enough that it comes completely off of the housing 540, which remains around the point 510. Whether this occurs or not does not affect the operation of the device 520, as the needle 504 is still readily unwound from the syringe 502 while the point 510 is captive in the housing 540. In addition, as the cover 522 cannot fit over the hub 508, after the syringe 502 is separated from the needle 504, the needle 504, cover 522 and housing 540 necessarily remain together.

The tab 562 on the chassis 560 fits within the recess 534 on the cover 522, to act as an additional anti-rotation device between the cover 522 and the housing 540 (in addition to the interaction of the bridge 578 against the side walls of the housing slot 530 on the cover 522) although whether the housing 540 turns with the cover 522 when the needle 504 is unwound, does not affect performance of the device 520.

While the present invention contemplates the wedging of the free end of surgical sharp between a gripping element and a portion of wedging element, alternative configurations of wedging, biasing, and gripping may be used. Pairs of gripping elements, separated by a spring or biasing element, can be used. With minor modifications, various sharps can be accommodated, such as flat blades, angled or curved blades or needles.

WHAT IS CLAIMED IS:

1. A safety device for a needle, comprising:
a housing having a thin, flat profile, a first opening and a second opening;
5 a cam pivotably mounted within the housing and displaceable to open and close off the first opening;
a spring within the housing; and
a gripper wheel within the housing between the spring and the cam.
- 10 2. The safety device of claim 1 further comprising a catheter fitting on the housing adjacent the first opening.
3. The safety device of claim 1 further comprising an inclined wall in the housing adjacent the second
15 opening.
4. The safety device of claim 1 further comprising a first leg on the cam adjacent the first opening and a second leg on the cam adjacent the second opening.
5. The safety device of claim 4 wherein the first
20 leg is wider than the second leg.
6. The safety device of claim 1 further comprising a catheter needle extending into the second opening and out of the first opening.
7. The safety device of claim 1 further comprising
25 serrations on the outer surface of the gripping wheel.
8. The safety device of claim 1 wherein the housing has a flat top surface and a flat bottom surface, to allow the housing to lie generally flat against the skin of a patient.

9. The safety device of claim 1 or 8 further comprising 2 tapered surfaces on the housing, to provide a thumb and finger grasping surface.

10. The safety device of claim 1 further comprising
5 a stay within the housing, positioned to slidably contact a needle extending through the housing.

11. A safety device for a needle, comprising:
a thin flat profile housing having a lower end
wall with a standard catheter fitting, a pair of
10 opposed parallel sidewalls joined to the lower end wall, and a pair of converging tapered sidewalls joined to the sidewalls and to an upper end wall;
a cam pivotably mounted on a pin in the housing, the cam having a first leg and a second leg, with the
15 first leg wider than the second leg;
a first opening through the fitting and a second opening in the upper end wall and aligned with the first opening;
a gripping wheel having a roughened outer surface
20 in contact with the second leg of the cam; and
a spring projecting from a spring receptacle in the housing, the spring in direct contact with the gripping wheel, and urging the gripping wheel against the second leg of the cam and towards one of the
25 tapered sidewalls.

12. A safety catheter comprising:
a needle point lock having a housing;
a needle assembly including a needle having a point and a needle shaft, with the needle shaft passing through
30 the needle point lock housing;
a catheter having a hub; and
catheter holding means for holding the catheter onto the needle point lock housing, until the needle point is drawn into the housing; and

locking means for locking the point of the needle within the housing.

13. The safety catheter of claim 12 further comprising a housing cover on the needle assembly adapted to fit
5 over the needle point lock housing.

14. The safety catheter of claim 13 further comprising a flash back chamber on the housing cover, connecting to the needle.

15. The safety catheter of claim 12 wherein the
10 catheter holding means comprises a locking arm having a hook extending outside of the needle point lock housing.

16. The safety catheter of claim 12 wherein the locking means comprises a ramp surface within the housing, a locking wheel on the ramp surface, and biasing means for
15 urging the wheel into the ramp surface and towards the needle shaft.

17. The safety catheter of claim 12 further comprising flanges on the hub of the catheter, and flange stops on the housing adjacent to the flanges.

20 18. The safety catheter of claim 12 wherein the catheter holding means comprises a retainer having a rear leg and a front leg joined by an arm section, with a hook on the front leg extending out of the housing to hold a catheter onto the housing.

25 19. The safety catheter of claim 18 further comprising a spring in the housing pushing against the rear leg.

20. The safety catheter of claim 12 wherein the catheter holding means comprises a push button having a lip engaged to a catch on a slide.

21. A safety catheter comprising:

a housing;

a retainer cam pivotably positioned in the housing,
the retainer cam having a first leg and a second leg, with

5 a hook on the second leg extending out of the housing;

a grip wheel within the housing;

a spring urging the grip wheel against the first end
of the retainer cam;

a catheter releasably secured to the housing by the
10 hook; and

a needle extending through the housing and through
slots in the first leg and the second leg.

22. The safety catheter of claim 21 wherein the
housing has a flat top and a flat bottom.

15 23. A safety device for a needle comprising:

a housing having a top wall including a needle
opening;

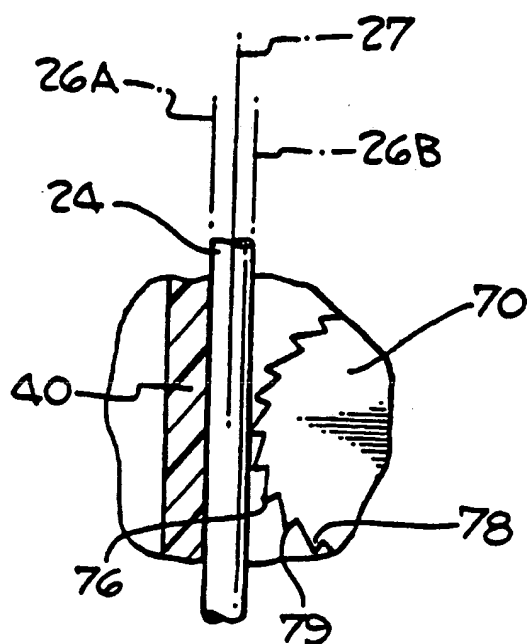
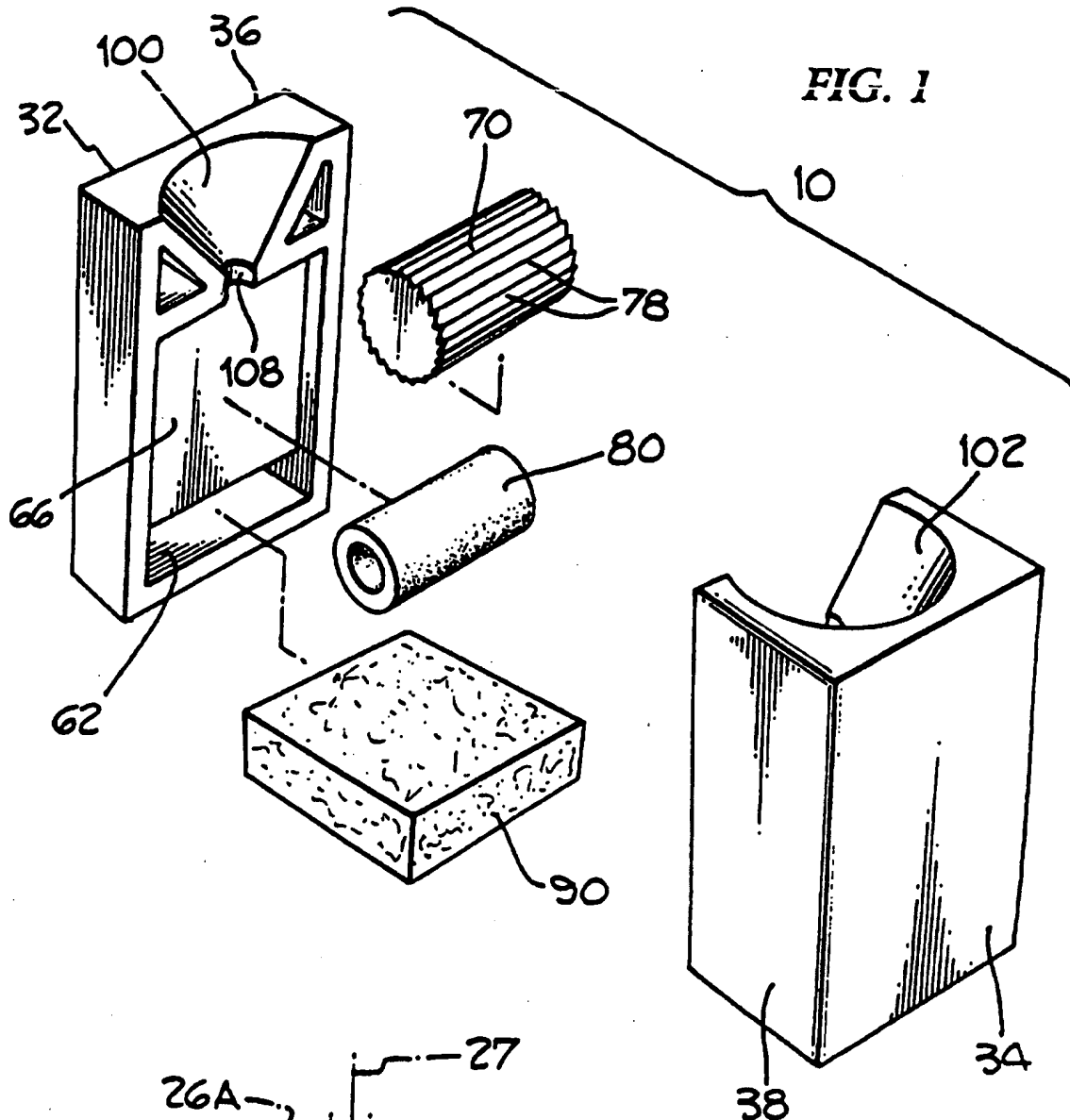
a chassis within the housing, the chassis having
a straight wall, an inclined wall forming an acute
20 angle with the straight wall, a gripping wheel and a
spring urging the gripping wheel towards the straight
wall and the inclined wall; and

a cover slidably positioned over the housing,
the cover having a conically tapering inlet
25 aligned with the needle opening, and a plurality
of splines on the inlet.

24. The safety device of claim 23 wherein the chassis
is slidably positioned within a chassis slot in the
housing.

30 25. The safety device of claim 23 further comprising
a bridge section on the housing and a bridge slot on the
cover.

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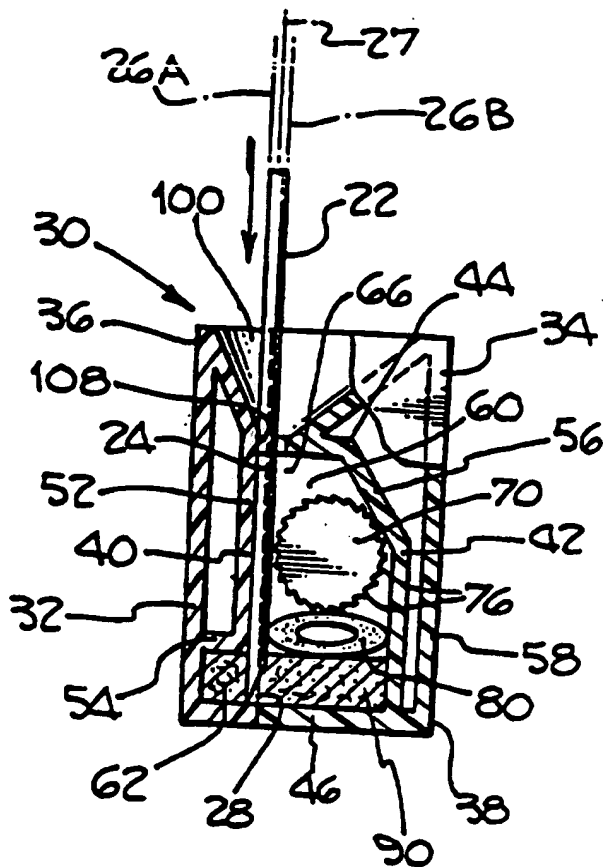
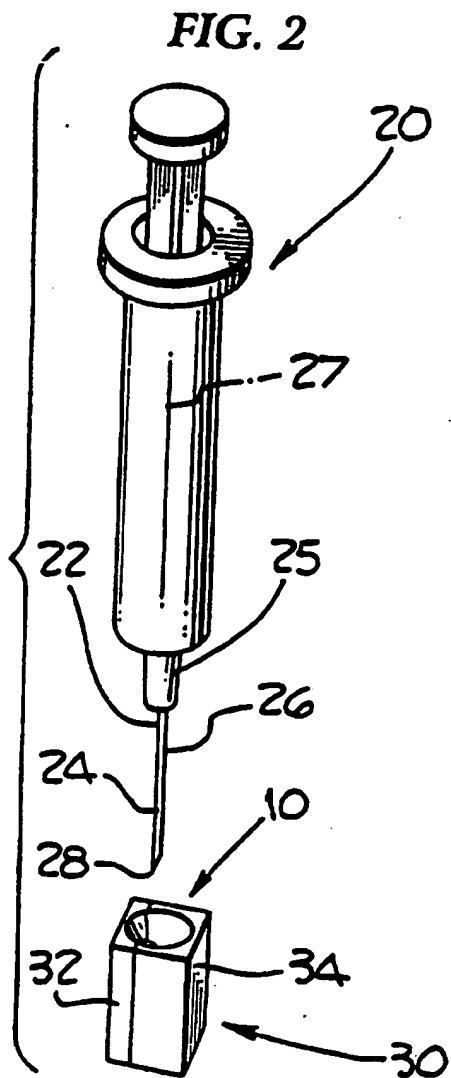


FIG. 5

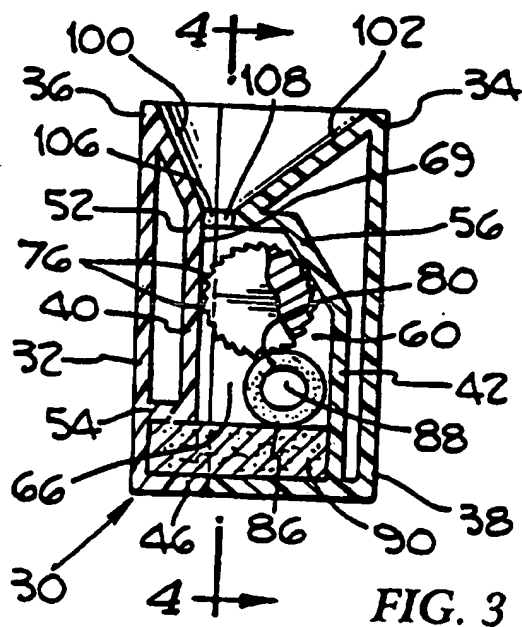
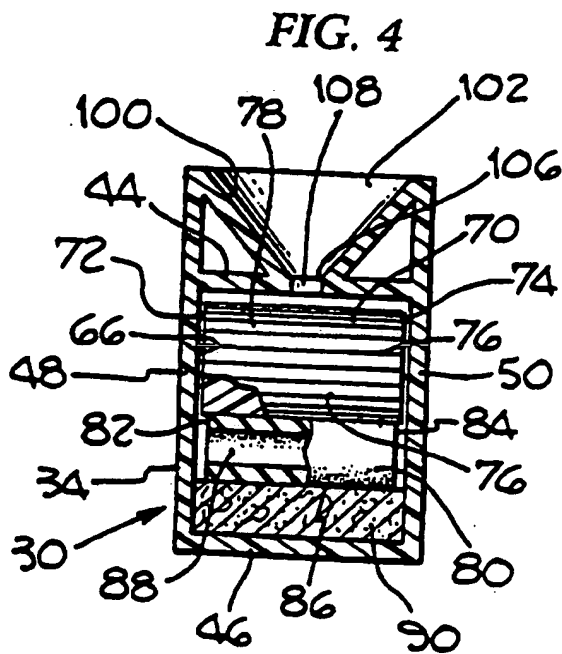


FIG. 3



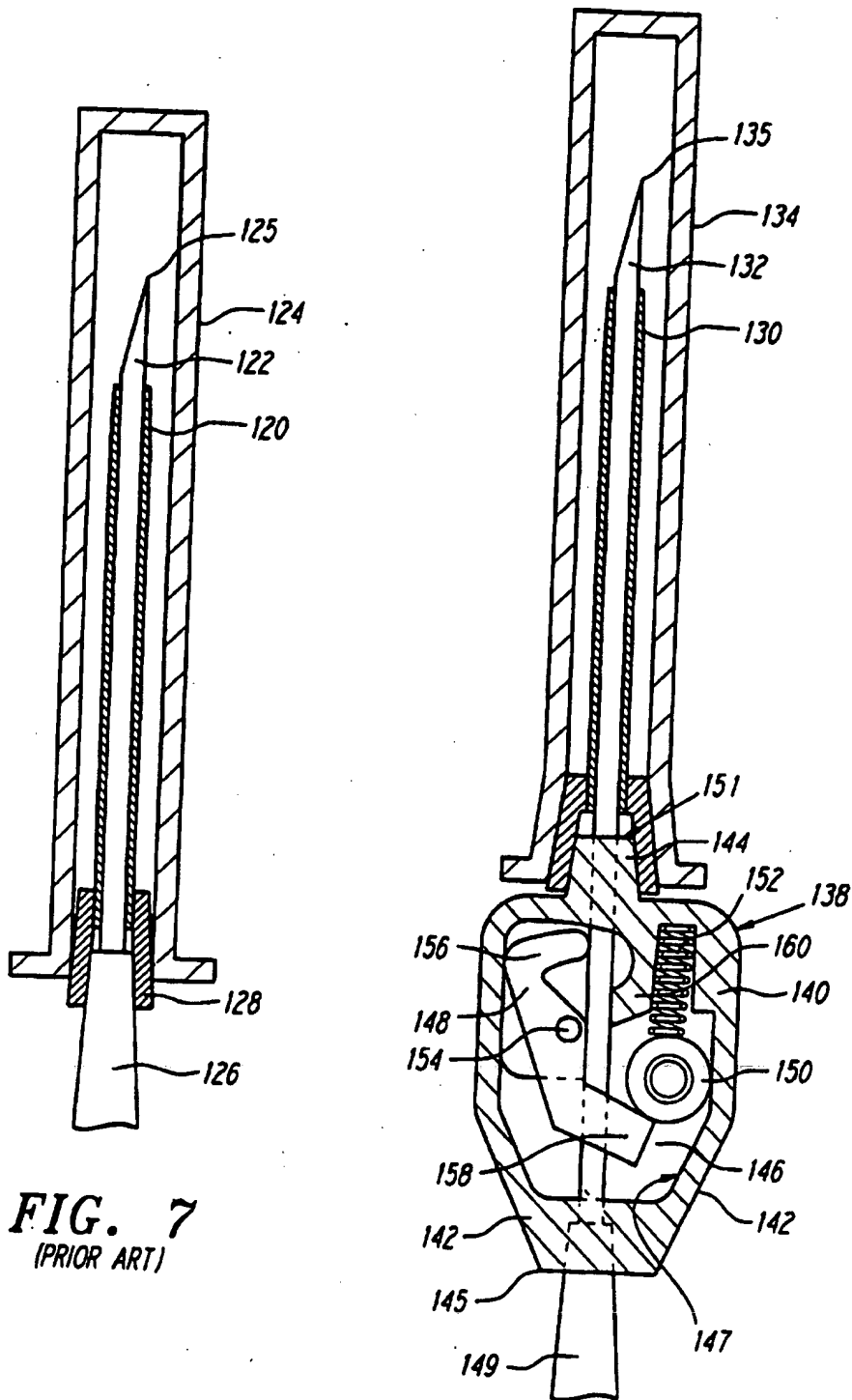
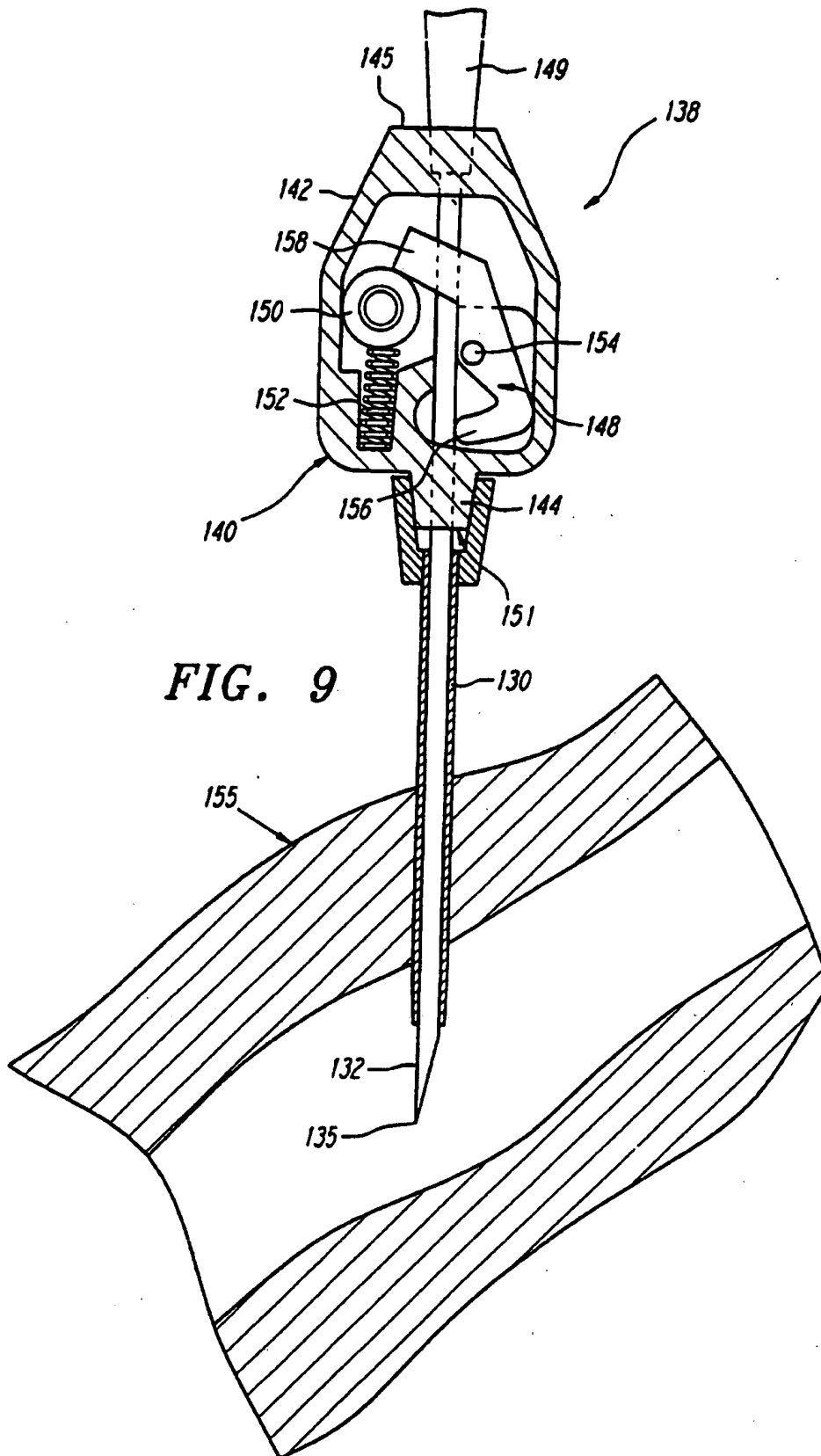
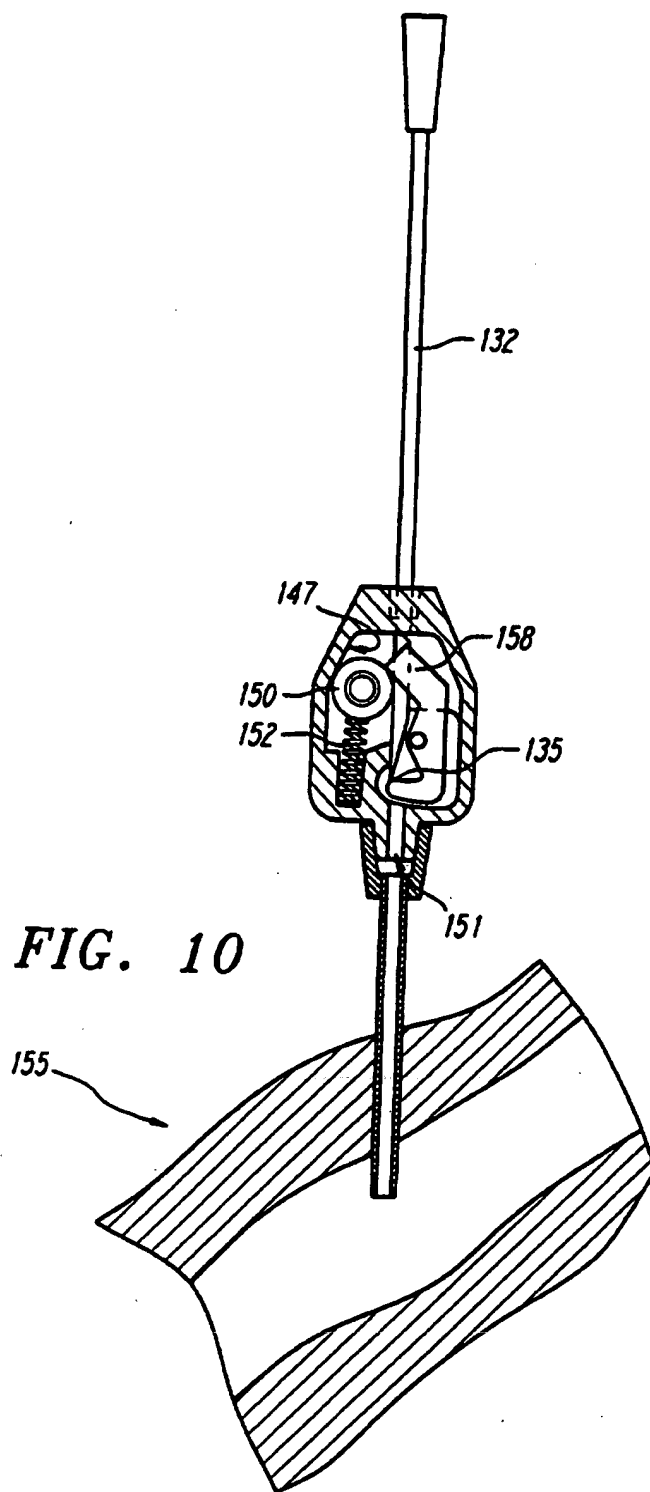
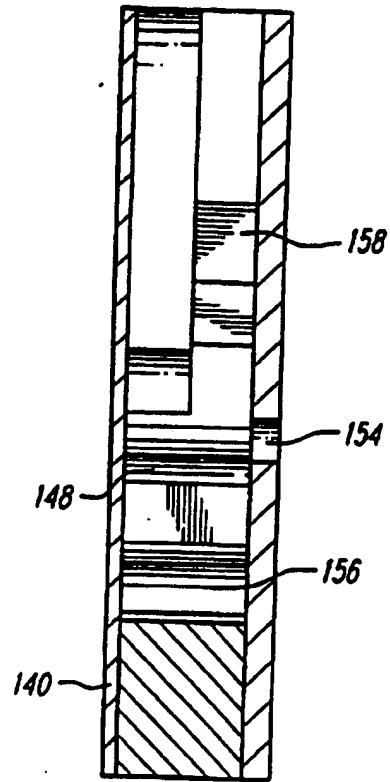
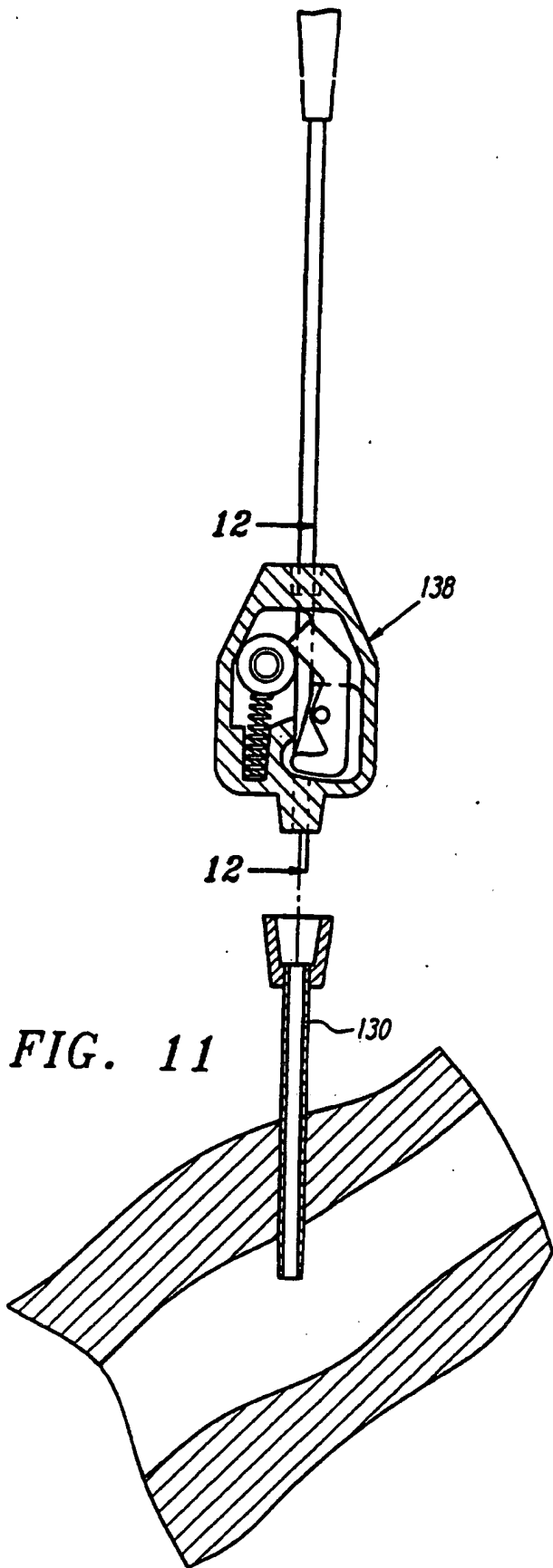


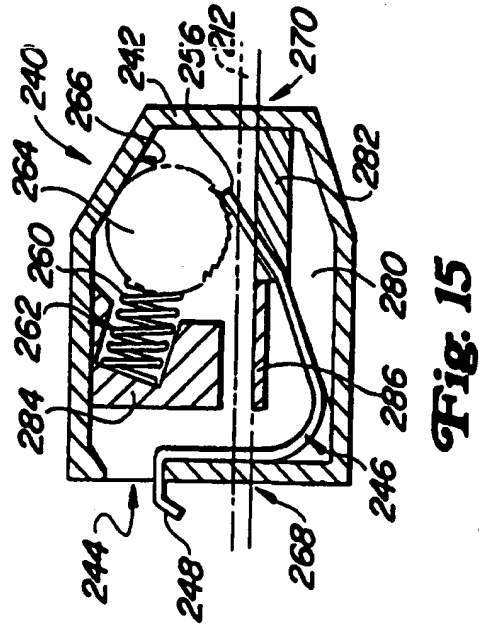
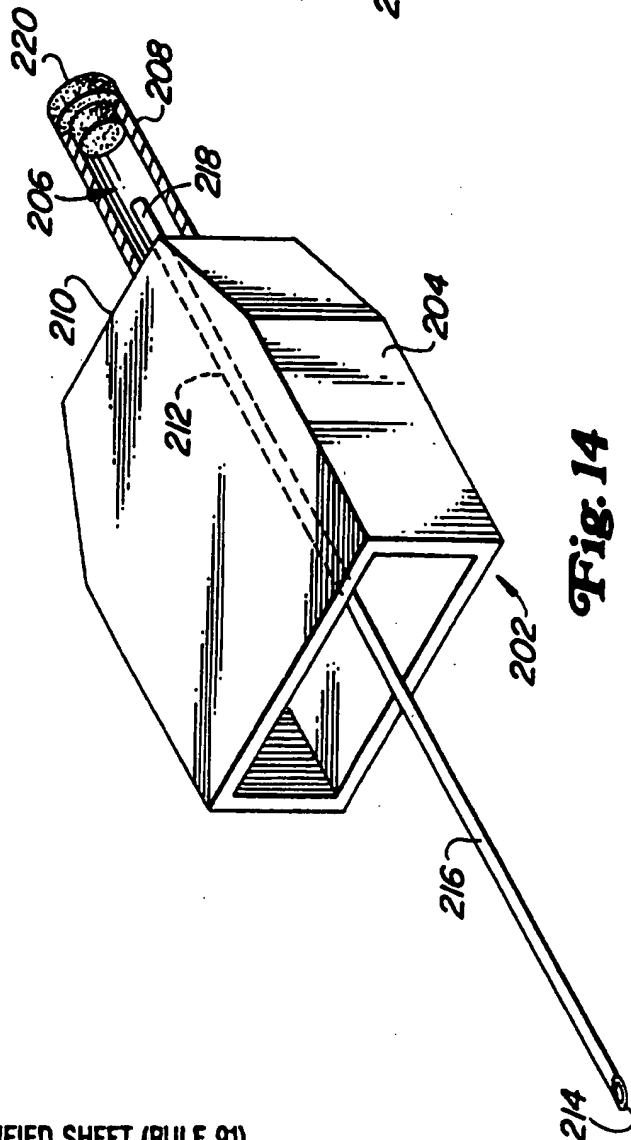
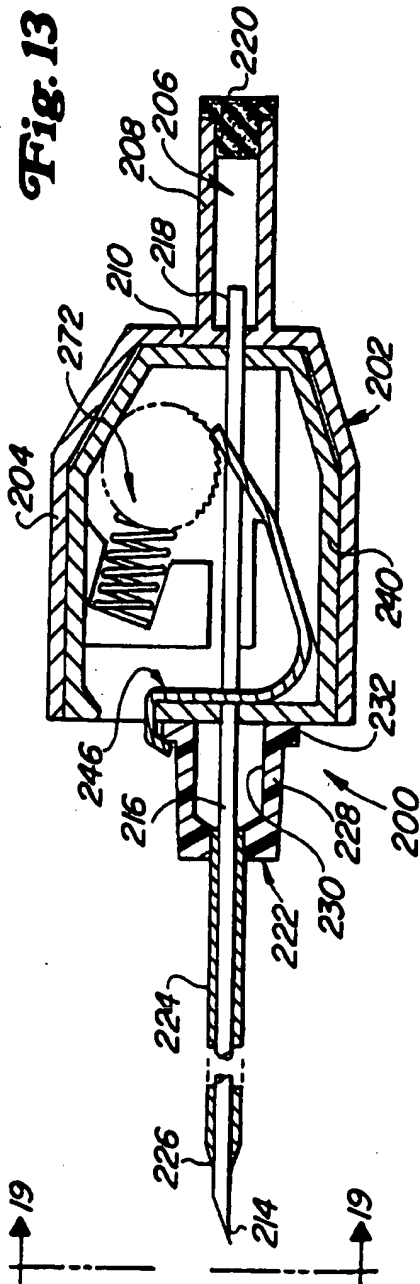
FIG. 7
(PRIOR ART)

FIG. 8









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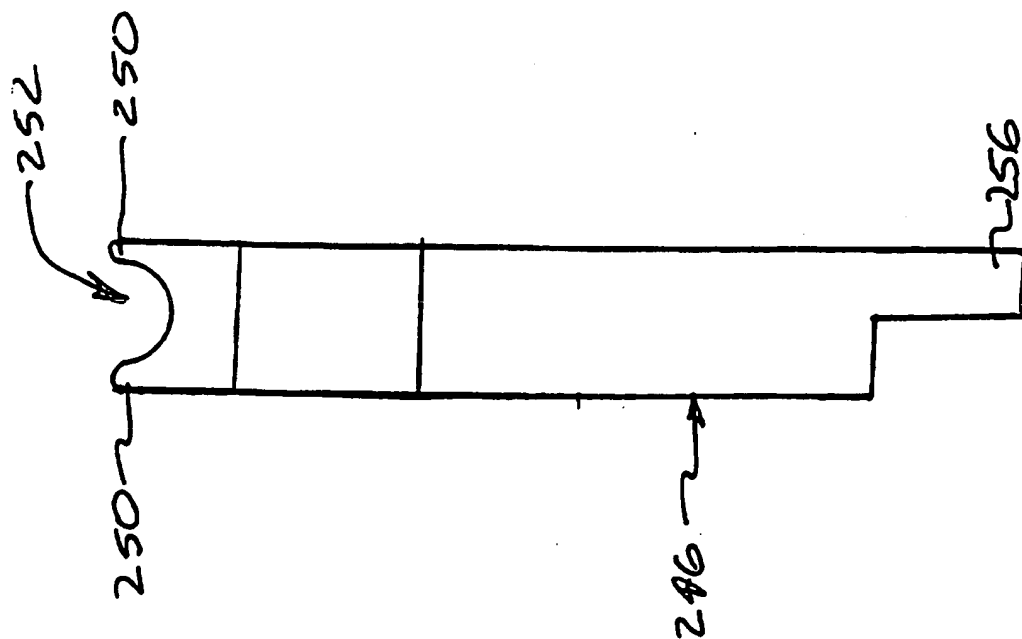


FIG. 16

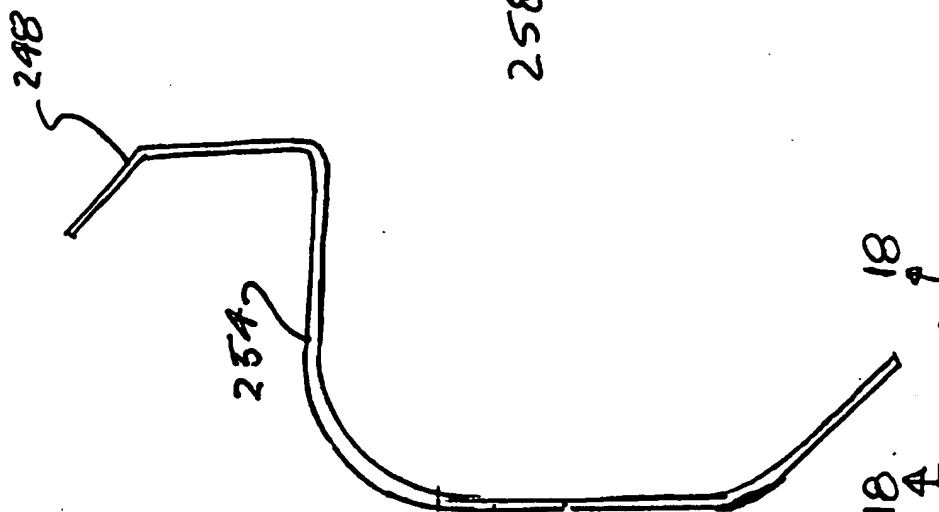


FIG. 17

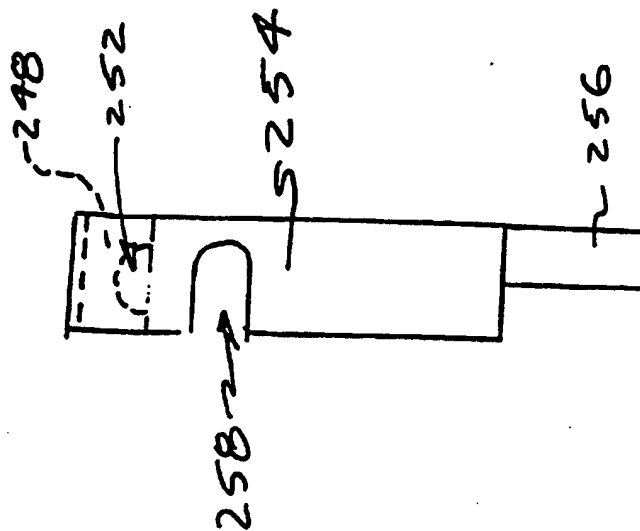


FIG. 18

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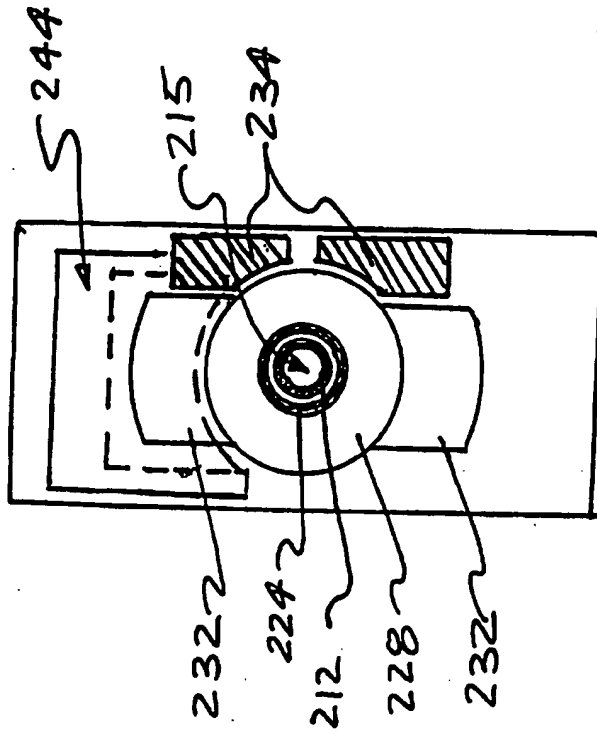


FIG. 19

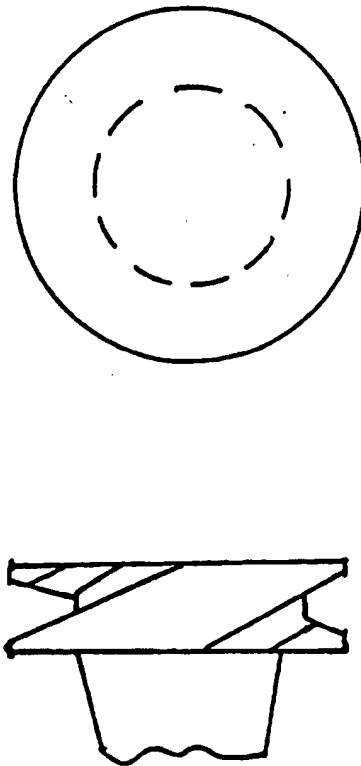


FIG. 19A

FIG. 19B

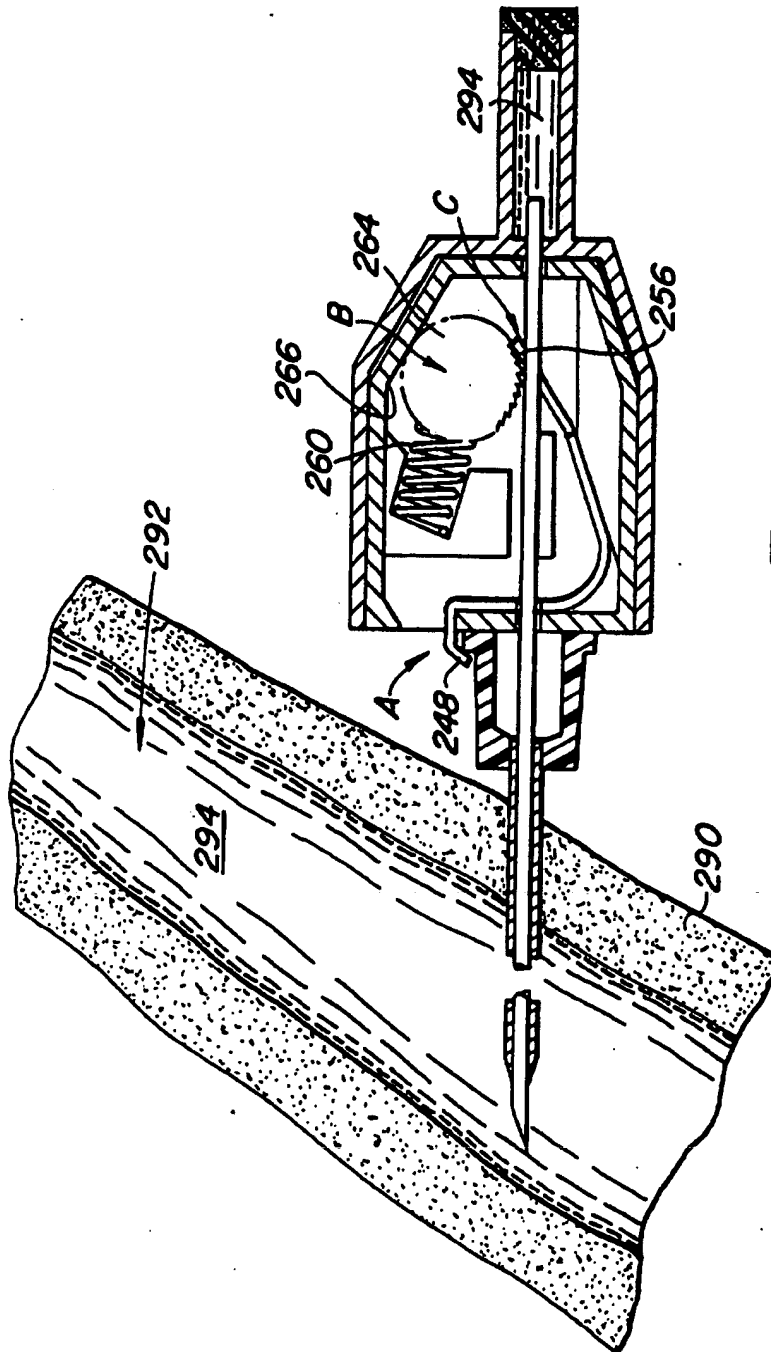


Fig. 20

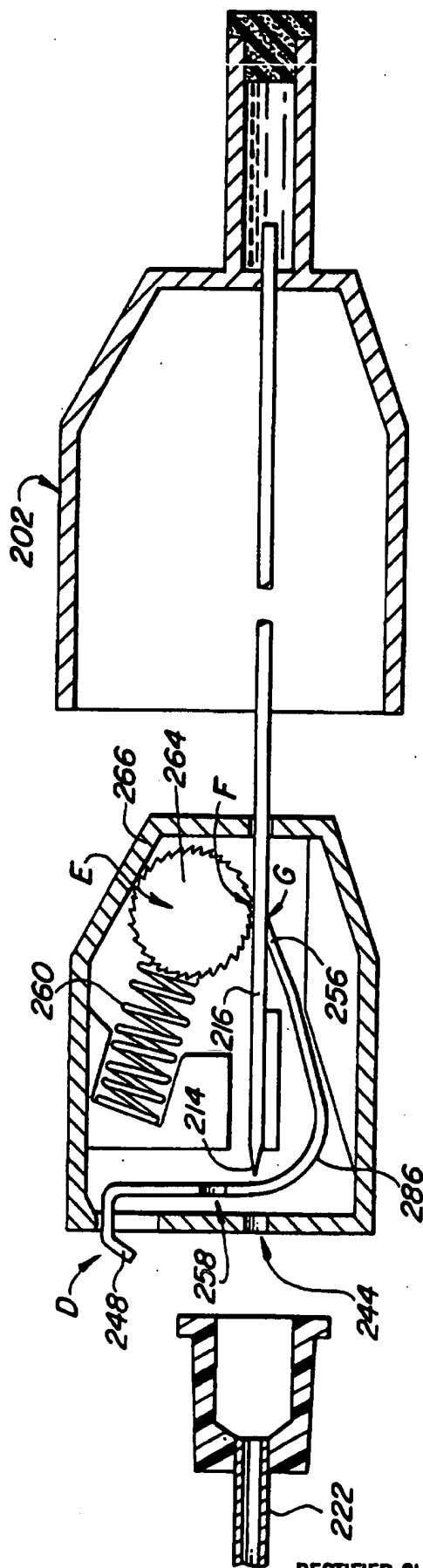


Fig. 21

Fig. 22

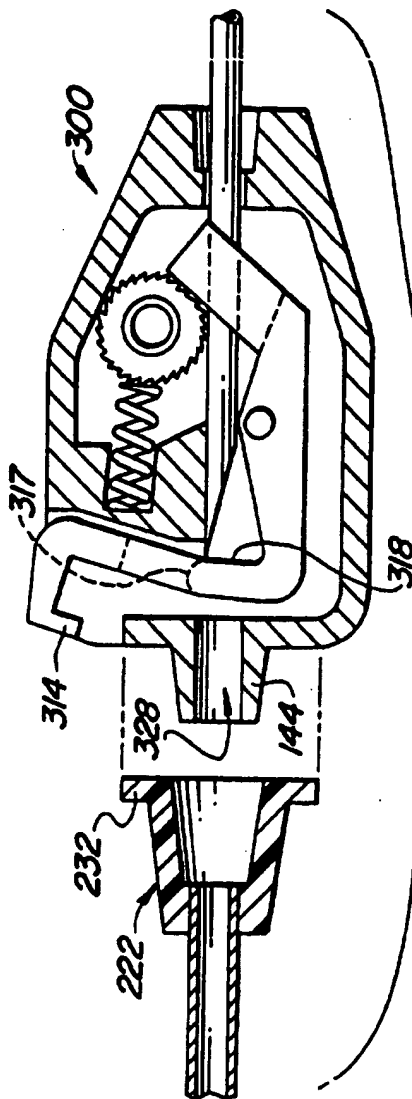
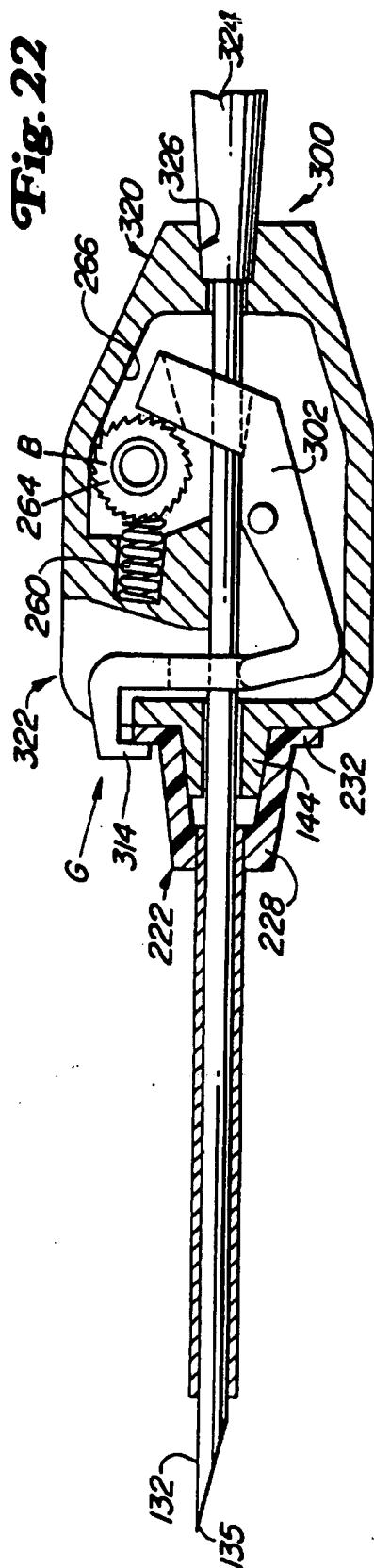


Fig. 23

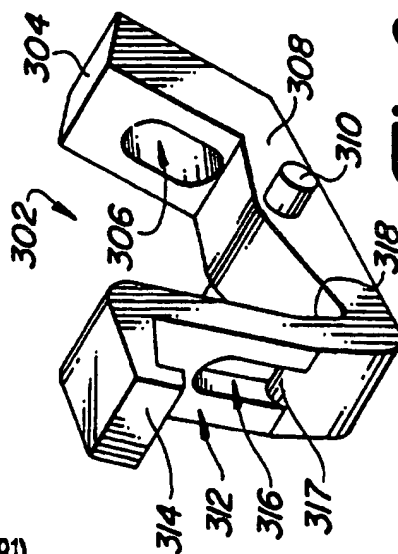
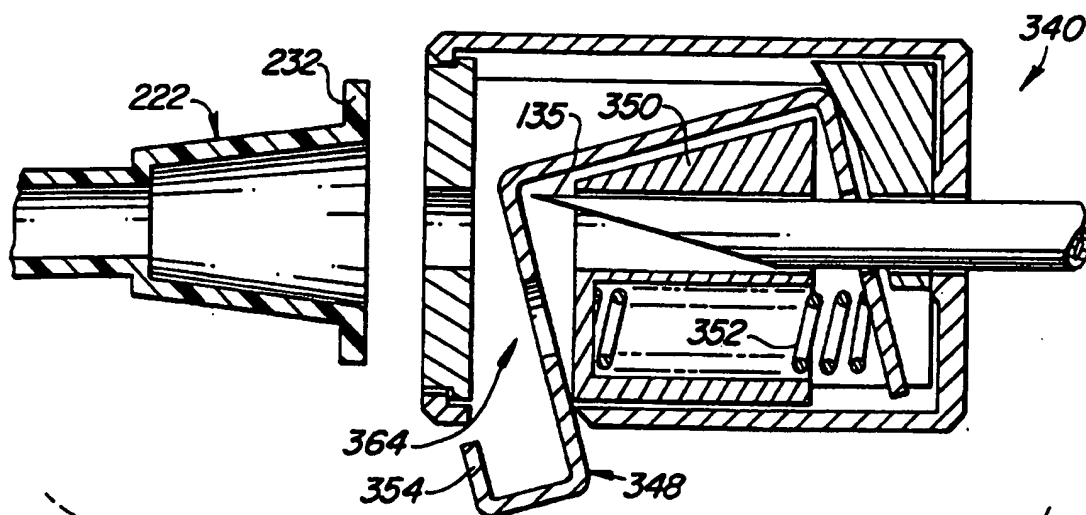
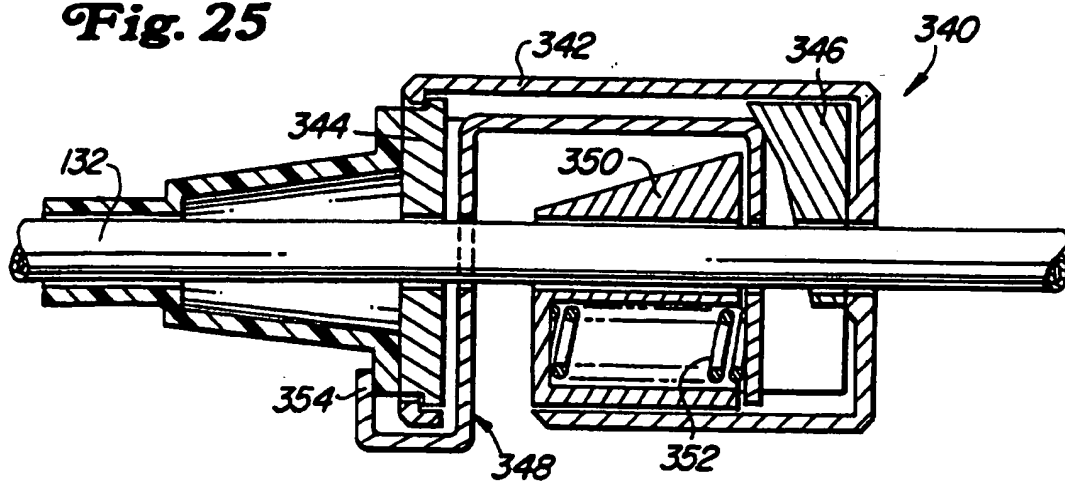
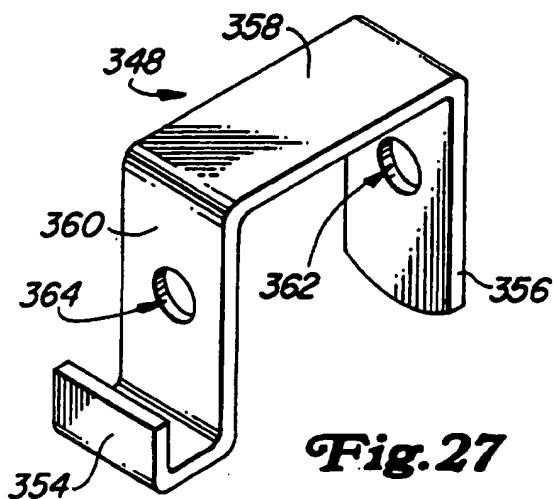


Fig. 24

Fig. 25**Fig. 26****Fig. 27**

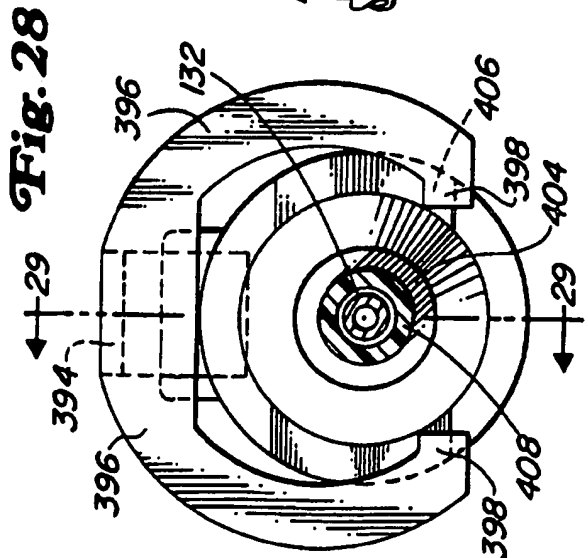
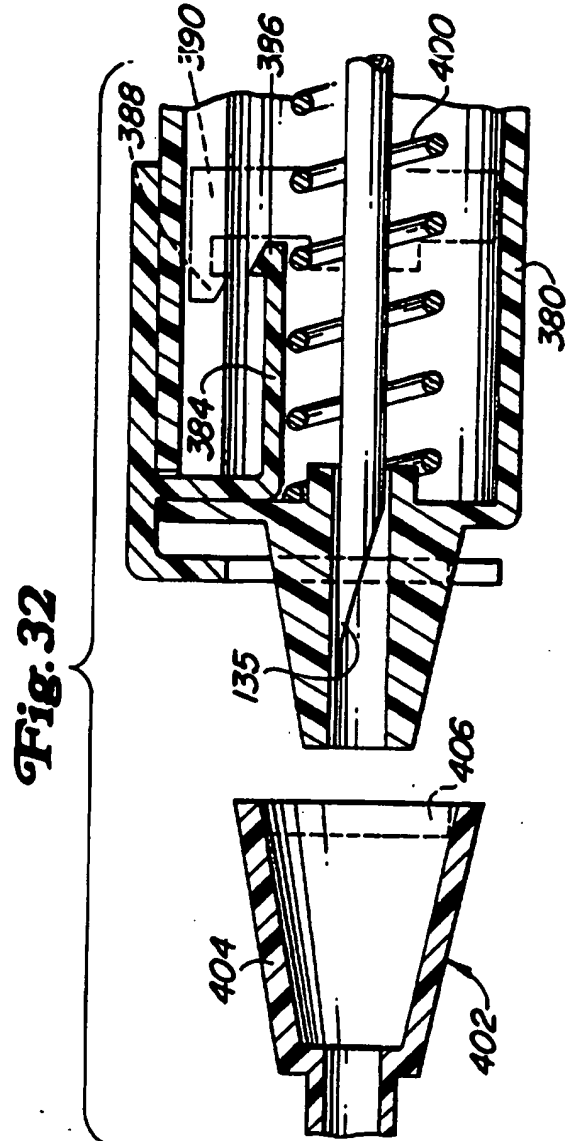
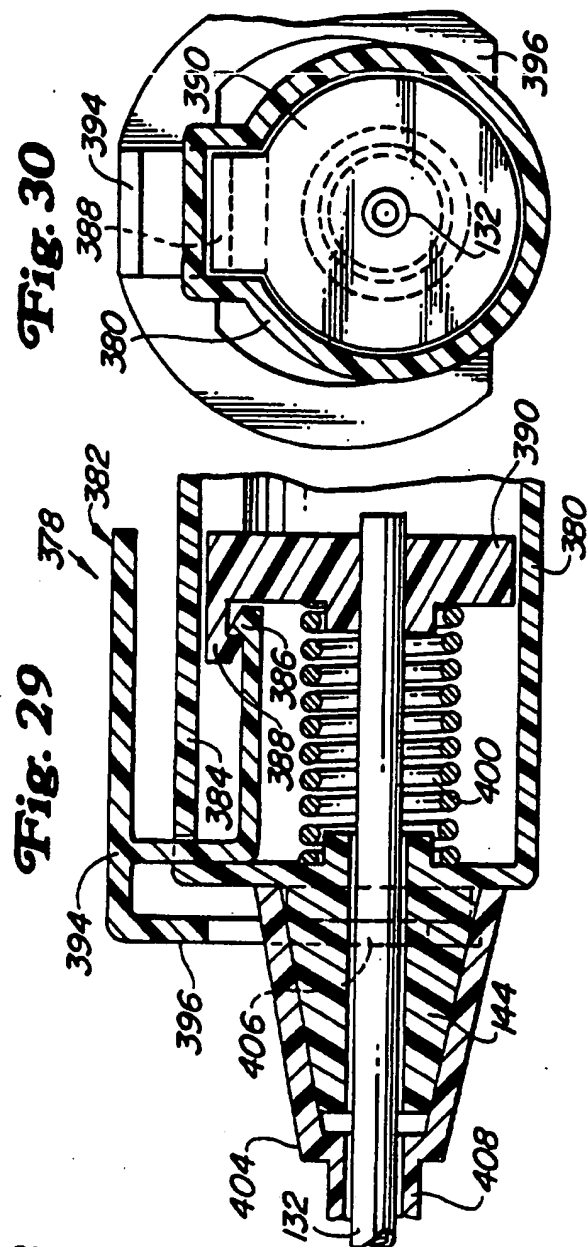
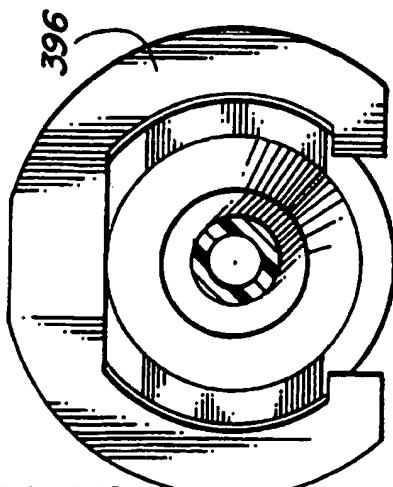


Fig. 31



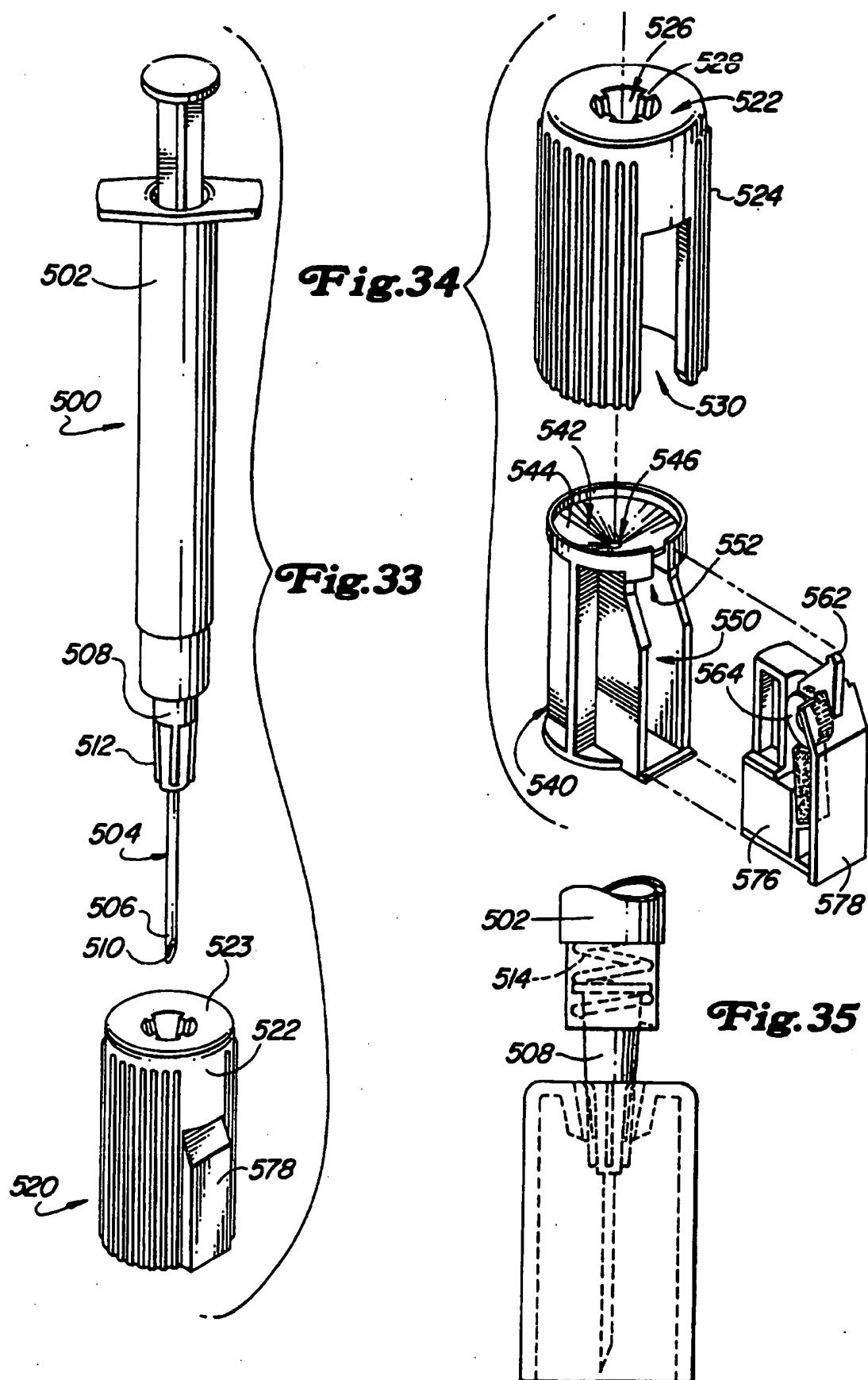


Fig. 36

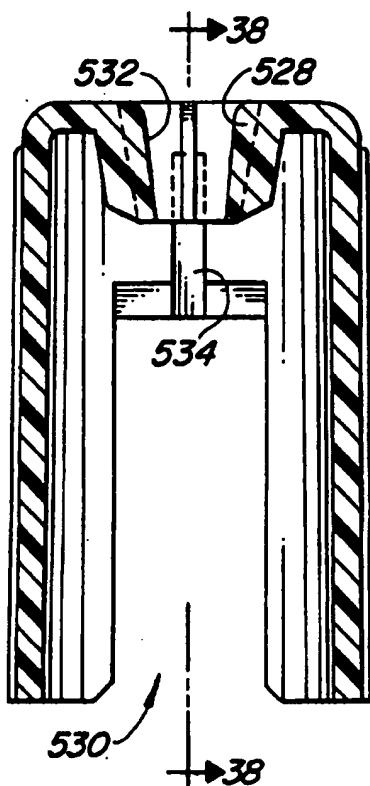
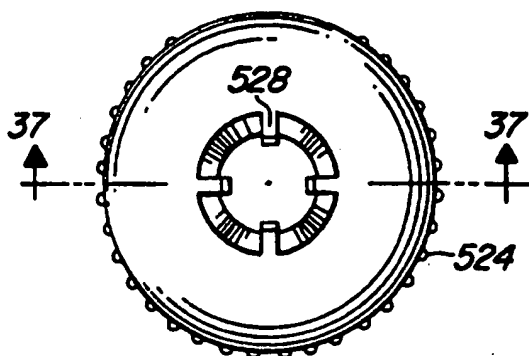


Fig. 37

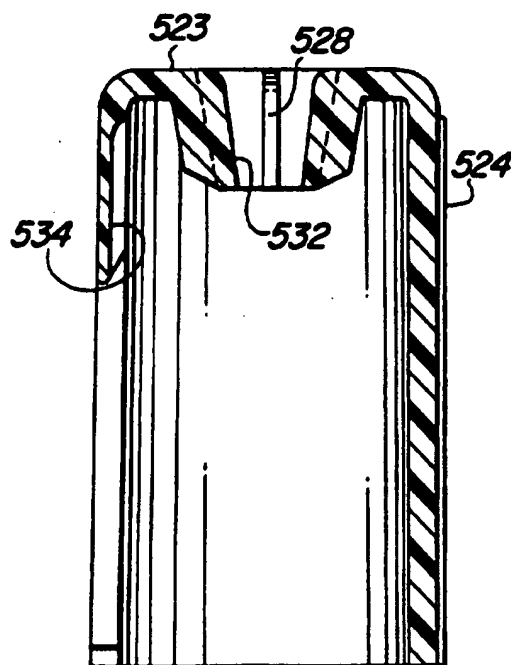


Fig. 38

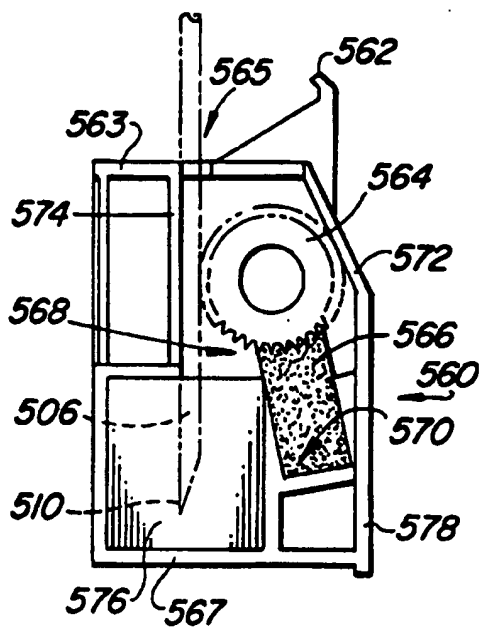


Fig. 39

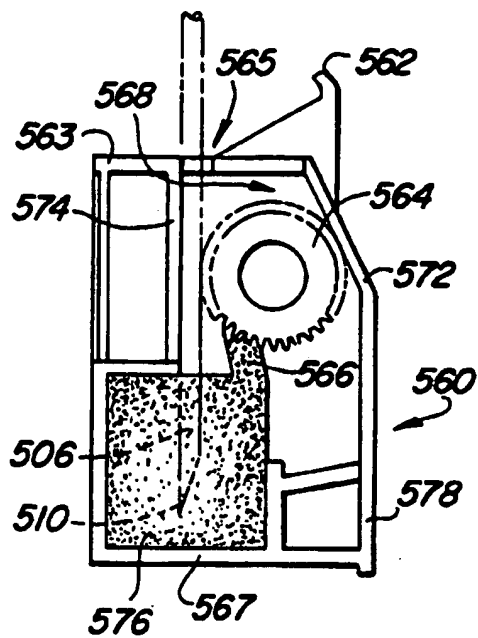


Fig. 40

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/00750

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6): A61M 5/32

US CL : 604/110

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 206/365, 366; 604/187, 192, 198, 163

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 5,195,983 (BOESE) 23 March 1993, see entire document.	1-28
A	US, A, 5,334,158 (McLEES) 02 August 1994, see entire document.	1-28
A	US, A, 5,328,482 (SIRCOM ET AL.) 12 July 1994, see entire document.	1-28

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	*T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
*A document defining the general state of the art which is not considered to be part of particular relevance	*X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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*O document referring to an oral disclosure, use, exhibition or other means	
*P document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

19 MARCH 1996

Date of mailing of the international search report

22 APR 1996

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
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